EUROPEAN COMMISSION

JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
European Chemicals Bureau
I-21020 Ispra (VA) Italy

DIPHENYL ETHER, PENTABROMO DERIVATIVE (PENTABROMODIPHENYL ETHER)

CAS-No.: 32534-81-9

EINECS-No.: 251-084-2

Summary Risk Assessment Report

2001 **Special Publication I.00.130**

DIPHENYL ETHER, PENTABROMO DERIVATIVE (PENTABROMODIPHENYL ETHER)

CAS No.: 32534-81-9

EINECS No.: 251-084-2

SUMMARY RISK ASSESSMENT REPORT

Final report, August 2000

United Kingdom

The scientific work on the environmental sections was carried out by the Building Research Establishment (BRE) Ltd, by order of the rapporteur.

Contact point

Environment: Environment Agency
Chemicals Assessment Section
Ecotoxicology and Hazardous Substances National Centre
Isis House, Howbery Park
Wallingford, Oxfordshire, OX10 8BD

Contact point

Human Health: Health & Safety Executive
Industrial Chemicals Unit
Magdalen House, Stanley Precinct
Bootle, Merseyside L20 3QZ

Date of Last Literature Search :	**1999**
Review of report by MS Technical Experts finalised:	**March, 2000**
Final report:	**August, 2000**

PREFACE

The report provides the comprehensive risk assessment of the substance Diphenyl ether, pentabromo derivate. It has been prepared by the United Kingdom in the frame of Council Regulation (EEC) No. 793/93 on the evaluation and control of the risks of existing substances. For detailed information on the risk assessment principles and procedures followed, the underlying data and the literature references, the reader is referred to the original risk assessment report that can be obtained from European Chemicals Bureau[1]. The present summary report should preferably not be used for citation purposes.

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

CONTENTS

1 GENERAL SUBSTANCE INFORMATION

The commercial substance is a mixture of related compounds, of which pentabromodiphenyl ether isomers comprise 50-62% w/w. General substance information and physico-chemical properties are shown in **Table 1**.

Table 1 Identification and properties of pentabromodiphenyl ether

Property	**Value/remark**
Molecular formula	$C_{12}H_5Br_5O$
Molecular weight	564.66 (70.8% bromine by weight)
Physical state at ntp	Amber, viscous liquid or semi-solid (commercial product)
Melting point	-7 to -3°C (commercial product)
Boiling point (at ntp)	Decomposes at > 200°C (commercial product)
Relative density	2.25-2.28 (commercial product)
Vapour pressure	$4.69 \cdot 10^{-5}$ Pa at 21°C (commercial product)
Water solubility	13.3 µg/l at 25°C (commercial product)
Log octanol-water partition coefficient	6.57 (measured; commercial product)
Flammability	Not applicable - flame retardant
Autoflammability	Not applicable
Explosive properties	None
Oxidising properties	None
Other components of the commercial product	Tribromodiphenyl ether 0-1% Tetrabromodiphenyl ether 24-38% Hexabromodiphenyl ether 4-2% Heptabromodiphenyl ether trace

The substance is referred to as pentaBDPE in this summary.

2 GENERAL INFORMATION ON EXPOSURE

PentaBDPE is used in the EU as a flame retardant additive for polyurethane (principally flexible foams for use in car seats, furniture and packaging) at typical loadings of 10% w/w. Several other uses have been reported in the literature (e.g. in textiles and electronics) but these are not currently known to occur in the EU. The risk assessment therefore only concerns use in polyurethane.

There are no producers of pentaBDPE in the EU. The import tonnage has been steadily declining in recent years and is currently < 150 tonnes/year (1999). It is not known how much enters the EU in polyurethane articles (an assumption of 1,100 tonnes/year is used in the assessment).

3 ENVIRONMENT

3.1 EXPOSURE

The major relevant characteristics of pentaBDPE are that it:

- is not readily or inherently biodegradable;
- has a high log K_{ow} value (6.57); and
- has an estimated atmospheric half-life of 12.6 days.

The high log K_{ow} value indicates that the substance will adsorb strongly onto sludge and sediments and is not expected to be mobile in soil. All the main components of the commercial substance bioconcentrate and the potential for uptake and accumulation of the substance by fish and other aquatic and terrestrial organisms is high. A measured fish bioconcentration factor of 14,350 l/kg has been reported in the literature.

The predicted fate of pentaBDPE in wastewater treatment plants is that 90.7% is adsorbed onto sewage sludge, 0.19% is released to air and 9.11% is released to surface water. The major emissions from industry are therefore expected to occur to water and to land via sewage sludge. Emissions to air are also significant over the lifetime of polyurethane articles containing the substance.

Emissions from the production of polyurethane foam have been estimated using information from the plastics industry in conjunction with the default release factors from the EU Technical Guidance Document (TGD). Emissions to the environment during the service life of foam articles are considered by analogy with other additives. Emissions arising from disposal have also been considered.

In summary, total emissions to air are predicted to be higher than to waste water, mainly as a result of volatilisation from the polymer product over its service life. There are no direct emissions to soil, but sewage sludge application and atmospheric deposition are predicted to be routes of release to soil.

3.1.1 Predicted environmental concentrations (PECs)

Concentrations in water, sediment, air, soil and biota (fish and earthworms) were estimated according to the methods in the TGD, and these are given in **Table 2.**

Table 2 Summary of PECs for commercial pentabromodiphenyl ether

Media	Release source	PEC
Surface water	Polyurethane foam production (local)	0.37 µg/l
	Regional sources	0.0015 µg/l
Sediment	Polyurethane foam production (local)	4.5 mg/kg wet wt.
	Regional sources	0.032 mg/kg wet wt.
Agricultural soil	Polyurethane foam production (local)	2.68 mg/kg wet wt.
	Regional sources	0.13 mg/kg wet wt.
Air	Polyurethane foam production (local)	28.3 ng/m^3
	Regional sources	0.27 ng/m^3
Secondary poisoning	Fish-based food chain: polyurethane foam production & use	4.38-8.36 mg/kg wet wt.
	Earthworm-based food chain: polyurethane foam production & use	34.3 mg/kg wet wt.

These predicted concentrations are generally supported by the available monitoring data, which also indicate that components of the substance are widely distributed in the environment (including predatory birds and mammals in remote areas). Some derivatives of brominated diphenyl ethers are known to occur naturally, but these do not account for all of the monitored data.

3.2 EFFECTS

Surface water

Short-term and longer-term toxicity test data are available for fish, invertebrates and algae. No effects were seen in acute toxicity tests with fish at concentrations in excess of the water solubility, but effects were seen in an 87-day fish early lifestage study at concentrations of 16 µg/l and above. The no observed effect concentration (NOEC) determined in this study was 8.9 µg/l. Effects were seen in algae over the first 24 hours at concentrations around 3.3-6.5 µg/l and above, but these had disappeared by 72 hours. For invertebrates, toxic effects were seen in both the short-term and long-term studies. The 48-hour EC_{50} for *Daphnia magna* was determined as 14 µg/l, and the 21-day reproduction study gave a NOEC of 5.3 µg/l. Based on this NOEC and an assessment factor of 10, a predicted no effect concentration (PNEC) of 0.53 µg/l is derived for surface water.

Sediment

Due to the physico-chemical properties of the substance, the sediment phase is much more relevant than the water phase. Prolonged toxicity tests with three sediment-dwelling organisms have been carried out and the lowest NOEC was 3.1 mg/kg dry weight (from a 28-day survival/reproduction test with *Lumbriculus variegatus*). This is equivalent to a $NOEC_{standard}$ of 15.5 mg/kg dry weight when normalised to the standard organic carbon content of sediment used in the TGD. From the experimental data it is not clear if this normalisation is appropriate for this substance and so two PNECs have been derived using each NOEC and an assessment factor of 10. The PNEC is 0.31 mg/kg dry weight and the $PNEC_{standard}$ is 1.55 mg/kg dry weight. Both PNECs lead to similar conclusions in the risk assessment (see below).

Wastewater treatment plant

There are no effects data available for sewage treatment microorganisms.

Terrestrial compartment

Toxicity studies have been carried out on plants, earthworms and soil-dwelling microorganisms. The lowest NOEC was obtained from the plant study, where effects were seen on two out of six species of plants tested. The NOEC was determined to be around 16 mg/kg dry weight, which is equivalent to a $NOEC_{standard}$ of 18.8 mg/kg dry weight when normalised to the standard organic carbon content of soil used in the TGD. Based on this NOEC and an assessment factor of 50, a PNEC of 0.38 mg/kg dry weight is obtained.

Atmosphere

The predicted atmospheric concentrations of pentaBDPE are all very low. Neither biotic nor abiotic effects are considered likely because of the limited release and low volatility of the substance.

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

The available information indicates that pentaBDPE has a high potential for bioconcentration and bioaccumulation. The available mammalian toxicity data allow a PNEC for secondary poisoning of 1 mg/kg food to be derived.

3.3 RISK CHARACTERISATION

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

- a possible local risk to the aquatic (sediment) compartment from local sources during the production of polyurethane foams;
- a possible risk to the soil compartment from local sources during the production of polyurethane foams; and
- a possible risk of secondary poisoning of top predators due to the production of polyurethane foams and their subsequent use.

It is not possible to carry out the PEC/PNEC comparison for sewage microorganisms since no toxicity data are available.

Another area of concern with regard to both direct toxicity and secondary poisoning is the possible formation of brominated dibenzo-*p*-dioxins and dibenzofurans from articles containing the substance during combustion or other high temperature processes (e.g. incineration, landfill (where fires could occur) or accidental fires). Overall it can be concluded that pentaBDPE, as a source of bromine, can contribute to (but is not the only source of) the formation of halogenated dibenzo-*p*-dioxins and furans generated during such processes. However, it is not possible to quantify the amounts or assess the environmental significance of these products.

Uncertainties

There is a general lack of information on the actual releases of the substance from its various lifecycle stages. As a result the assessment is based on “realistic worst case” estimates, using the best available information and estimation methods. These estimates are conservative but are in general supported by the available monitoring data. The main areas of uncertainty in these estimates arise from:

- the emission factors based on default values or extrapolated from other substances rather than from direct measurements;
- unknown amounts of substance imported into the EU in finished articles;
- unknown long term trend in usage; and
- the applicability of some of the models used (for example, the earthworm uptake model and the root crop uptake model).

The main use of pentaBDPE in the EU is in polyurethane foams. There is some evidence that it may be present in some other polymeric materials, and there may have been other historical uses. Such articles may also be imported into the EU, and the actual amount of substance involved is unknown. A quantitative risk assessment for these potential uses is therefore not possible, but any emissions of the substance from these products could contribute to the regional diffuse emissions, and hence regional concentrations.

Regional emissions to the environment from the disposal phase of products containing the substance, for example from landfills and incinerators, are difficult to quantify and are not currently included in the PEC estimates (their contribution has been considered in a qualitative way in the main report). It is possible that in the long term levels may increase as a result of releases from waste sites.

Finally, the implications of the presence of the substance in the tissues of higher organisms are also uncertain. Future rises in tissue concentrations in terms of life-time exposure could be considered further in any future revision of the risk assessment report.

4 HUMAN HEALTH

4.1 EXPOSURE ASSESSMENT

4.1.1 Occupational exposure

Occupational exposure may occur during the production of flame retardant-containing polyurethane foams and during end product manufacture. The potential for inhalation exposure to pentaBDPE in the occupational setting is considered to be very low, particularly in view of its very low saturated vapour pressure. Exposure to the vapour will not exceed the saturated vapour concentration of $7 \cdot 10^{-4}$ ppm at ambient temperature. Where pentaBDPE is heated the vapour pressure will rise with a concomitant increase in the SVC. Increases in temperature may lead to some increase in volatilisation of pentaBDPE; however, this vapour will quickly condense to form a mist. Situations where exposure to mist is possible are likely to be controlled as a result of the nature of the work or the presence of substances of greater concern. During the manufacture of articles from polyurethane foam containing pentaBDPE, exposure will be significantly lower than industries using pentaBDPE itself.

There are no measured data on dermal exposure, but modelled data suggest that this may be the most significant route of exposure in workers. Dermal exposure may occur during the handling of receptacles containing PentaBDPE, when coming into contact with vessels and surfaces that have become contaminated from spillages and when handling polyurethane foam containing pentaBDPE or coated fabrics. Dermal exposure was predicted to be up to 0.1 mg/cm^2/day using EASE modelling refined for the duration of exposure or concentration of pentaBDPE in the formulation.

4.1.2 Consumer exposure

The current use pattern provided by industry is that pentaBDPE is only used in polyurethane foam and that consumers do not come into direct contact with these foams. The foam is only used in ways in which it is enclosed and therefore it is concluded that exposure to consumers is negligible.

4.1.3 Indirect exposure via the environment

The maximum total daily adult human intake of commercial pentaBDPE via the environment is estimated by the EUSES model to be 0.048 mg/kg/day via local sources and $7.9 \cdot 10^{-4}$ mg/kg/day via regional sources.

4.2 EFFECTS ASSESSMENT: HAZARD IDENTIFICATION AND DOSE (CONCENTRATION) - RESPONSE (EFFECT) ASSESSMENT

There is limited information regarding the absorption, metabolism and excretion of pentaBDPE in humans or animals. The available information suggests that pentaBDPE may be well absorbed by all routes of exposure. Once absorbed, there appears to be little metabolism. PentaBDPE and/or its metabolites is distributed to and retained in the fatty tissue. Excretion occurs via the biliary and faecal routes, as well as via breast milk. There is the potential for bioaccumulation of pentaBDPE.

The toxicity database for pentaBDPE is limited, but the minimum data requirements according to Article 9(2) of Regulation 793/93 have been met. PentaBDPE is of low acute toxicity by all routes of exposure. It lacks significant irritant properties, with respiratory tract irritation occurring only at very high exposure concentrations. PentaBDPE also lacks sensitisation potential. A NOAEL of 1 mg/kg/day can be identified from repeated dose oral studies in rodents which indicate that the liver is the principal target organ affected by pentaBDPE. A repeated dose dermal study in the rabbit ear model indicates that pentaBDPE has the potential to induce a 'chloracne-like' response. Available *in vitro* data indicate that pentaBDPE would not be mutagenic *in vivo*. There are no carcinogenicity data available. There are no fertility studies available for pentaBDPE, but in a well conducted 90-day study no histological changes were observed in the gonads or accessory sex organs of either sex at doses up to 100 mg/kg/day. In a developmental study, no evidence for specific developmental toxicity was seen with pentaBDPE when tested up to maternally toxic doses. A study investigating possible neurobehavioural effects in neonatal mice is available, the results of which suggest differences in behavioural patterns between treated and control animals. However, given the limitations of the study reporting and statistical analysis it is difficult to drawn any firm conclusions from this study with respect to the significance of the differences observed and any relevance to human health.

4.3 RISK CHARACTERISATION

4.3.1 Human health (toxicological properties)

4.3.1.1 Workers

There are considerable uncertainties regarding the characterisation of risks to workers. These uncertainties relate to the extent of inhalation and dermal exposure, the extent to which dermal absorption may contribute to the overall body burden, the mechanism of the 'chloracne-like' response observed in the rabbit ear study, the human health significance of the rodent liver effects and the approach to risk assessment for this substance, given its bioaccumulative potential. Hence, at this stage, it is not possible to fully characterise the risk to human health for occupational settings. Further information to address the uncertainties is required.

4.3.1.2 Consumers

Exposure to pentaBDPE is negligible, therefore there are negligible risks to consumers.

4.3.1.3 Indirect exposure via the environment

As for the risk characterisation for workers, there are considerable uncertainties associated both with the toxicity data available and the approach to the risk characterisation for a bioaccumulative substance. In addition, there are uncertainties with respect to the modelled exposure data used for local sources of exposure. Consequently further information is required to address these uncertainties.

4.3.1.4 Combined exposure

The combined exposure is dominated by the occupational exposure. The estimates of both occupational exposure and exposure via the environment are derived from models and these

estimates require refinement. In addition, as for workers, there are uncertainties surrounding the risk characterisation. Hence, further information is required to address these uncertainties.

4.3.1.5 Exposure to infants via milk

The risk characterisation for infants exposed via milk (human breast milk and cows' milk) is based on numerous assumptions regarding the pentaBDPE content of milk, the feeding infant and regarding the significance of toxicological endpoints of concern to the neonate. Thus the conclusion of the risk characterisation is that further information is required to address these uncertainties.

However, following the agreement of the risk assessment conclusions reached on a technical basis, Member States noted the uncertainties expressed regarding the risk characterisation for infants exposed to pentaBDPE from human breast milk. They also noted the conclusion that further information would be required to remove these uncertainties and refine the risk assessment. Member States were concerned that it would take a significant time to gather the information and that the resulting refined risk assessment could then indicate a risk to breast-feeding infants. Furthermore, the bioaccumulative properties of the substance could cause concentrations in breast milk to rise while the data was being gathered. Consequently Member States agreed that risk reduction measures should be considered without delay for the sources of this exposure.

4.3.2 Human health (physico-chemical properties)

PentaBDPE has a very low vapour pressure, no explosive or oxidising properties and retards combustion. It does have a high viscosity and is likely to cling to human tissue but this can be easily avoided by gloves. Therefore, it can be concluded that there is no cause for concern for human health arising from the physico-chemical properties.

5 OVERALL CONCLUSIONS

PentaBDPE is used as an additive flame retardant mainly in the polyurethane foam industry. The following conclusions relate to this use.

5.1 ENVIRONMENT

Local releases of pentaBDPE to the environment may occur from the manufacture and processing of polyurethane foam. In addition, losses may occur during the lifetime of finished articles (e.g. due to volatilisation or loss of particulates). These releases have been quantified in the assessment and used to calculate PECs for various environmental compartments. Releases to the environment could also occur from the disposal of finished articles (e.g. to landfill). It has not proved possible to quantify fully the releases from disposal and so these have been considered qualitatively in the assessment.

Results

Conclusion i) There is a need for further information and/or testing.

There is a data gap for toxicity to sewage microorganisms. A test on sewage treatment plant microorganisms would be required if this data gap were to be filled.

It is possible that in the long term levels in all compartments may increase as a result of releases from waste sites. This, and life-time exposure, may need to be considered further in any future revision of the risk assessment report.

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

This applies to the aquatic (surface water and sediment) compartment and the terrestrial compartment at the regional level, the aquatic (surface water) compartment at the local level, and to the assessment of atmospheric effects.

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

This applies to the local assessment for sediment and the terrestrial compartment. It also applies to the assessment of secondary poisoning arising from use in polyurethane foams, due to both local releases from foam production sites and diffuse releases arising from use of the foam. Once released to the environment from both point and diffuse sources, the substance appears to be transported widely and accumulates through the food chain.

It should also be noted that although not a formal conclusion of the risk assessment, the properties of the substance and evidence of long-range transport indicate that it may need to be considered further by other regulatory bodies dealing with persistent organic pollutants (POPs) which may be transported long distances in the atmosphere.

5.2 HUMAN HEALTH (TOXICOLOGICAL PROPERTIES)

5.2.1 Occupational Exposure

The estimated body burden of pentaBDPE arising from occupational exposure, chiefly via dermal contact, is approximately 4-fold greater than the NOAEL of 0.45 mg/kg/day for rodent liver effects. However, there are considerable number of uncertainties in this analysis, relating to the extent of occupational exposure, the extent of dermal absorption, the human health significance of the rodent liver effects and the approach to the risk assessment for a bioaccumulative substance.

Overall, these uncertainties indicate that the method used to calculate the margins of safety (MOS) used in the risk characterisation has significant limitations and that further information, including the development of a suitable methodology for the risk assessment of bioaccumulative substances is required.

Result

Conclusion i) There is a need for further information and/or testing.

Information is needed on the extent of dermal exposure in workers.

The extent of dermal absorption (quantitative data) should be clarified by the conduct of an appropriate dermal absorption study; depending upon the outcome of this study, it may be necessary to undertake an oral toxicokinetic study in order to provide adequate comparative information for interpretation of the oral dosing toxicity studies available.

Health surveillance data are required to investigate signs of chloracne in workers.

Further information should be obtained on the effects of prolonged (e.g. lifetime) exposure for a substance that has the potential to accumulate within the body. A methodology should be developed to address this situation. This may involve the conduct of a lifetime study in rodents depending upon the way in which the methodology for assessing lifetime exposure is developed and any data requirements that may be indicated for such a methodology.

5.2.2 Consumers

Consumer exposure to pentaBDPE is negligible since in the EU it is only used in polyurethane foam enclosed in products. It follows that risks to consumers are also negligible.

Result

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

5.2.3 Indirect exposure via the environment

There are considerable uncertainties associated both with the toxicity data available and the approach to calculating the MOS for indirect exposure via the environment, and also with respect to the modelled exposure data used for local sources of exposure. Thus the uncertainties outlined for the worker risk assessment also apply to the exposure scenarios of regional and local sources of exposure and consequently further information is required, as indicated for workers. Furthermore the estimates of local exposure are based entirely on modelled data, thus introducing an additional degree of uncertainty into the calculation of the MOS. In order to refine the calculation of the MOS and the risk assessment for local sources of exposure further information relating to actual measured exposure data is required.

Results

Conclusion i) There is a need for further information and/or testing.

For risk of liver effects via both regional and local sources of exposure further information should be obtained on the effects of prolonged (e.g. lifetime) exposure for a substance that has the potential to accumulate within the body. A methodology should be developed to address this situation. This may involve the conduct of a lifetime study in rodents depending upon the way in which the methodology for assessing lifetime exposure is developed and any data requirements that may be indicated for such a methodology.

Information is required relating to actual measured exposure data from local sources.

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

This relates to the potential development of a 'chloracne-like' response. Although a NOAEL cannot be identified from the available data, levels of exposure via local and regional sources are very low. It is, therefore, predicted that any risk to human health is likely to be minimal.

5.2.4 Combined exposure

The MOS values from the risk characterisation for both liver effects and behavioural effects are unacceptably low. The combined exposure is dominated by the occupational exposure. The estimates of both occupational exposure and exposure via the environment are derived from models. The estimates require revising either by refinement of the models or the provision of measured data in order to determine whether risk reduction measures should be considered. In addition, as described for workers, there is a need to obtain information on the effects of prolonged (e.g. lifetime) exposure for a substance that has the potential to accumulate within the body.

Result

Conclusion i) There is a need for further information and/or testing.

The further information required is that described previously for workers and for indirect exposure via the environment.

5.2.5 Exposure to infants via milk

For infants fed human breast milk the calculated MOS values are very large. However, there are considerable uncertainties in the analysis used to derive the MOS values. These uncertainties are such that it is currently not possible to say whether or not these MOSs provide reassurance of little or no risk to the breast feeding infant either at the present time or in the future. Much of the uncertainty could be reduced by the gathering of further information.

Result

Conclusion i) There is a need for further information and/or testing.

The following information is required:

- information on the toxicokinetics of pentaBDPE with respect to breast milk including uptake from breast milk into the infant, the time course of the excretion via breast milk during lactation in humans and the future trends in levels in human breast milk;

- information on the relative toxicity to the liver of pentaBDPE in young (neonatal) and adult animals;

- further studies on potential effects on behaviour following neonatal dosing in order to determine the reproducibility of effects, the effects of repeated dosing and the significance of the effects to human development;

- a multi-generation reproduction study in order to investigate whether or not other effects might be observed through exposure to breast milk. Designed correctly, such a study could address the issue of whether or not the young animal is more sensitive to liver effects and whether or not differences in behaviour are produced.

For infants fed cows' milk, estimates for the concentration of pentaBDPE in cows' milk using the EUSES model are higher than (local sources) or similar to (regional sources) the measured levels found in human breast milk. Given that intake of cows' milk can be similar to, or greater than, that of human breast milk during the first year of life, it is likely that similar or slightly higher MOS values would be calculated for this exposure scenario. These calculations would also be subject to some of the uncertainties outlined above. In addition, given that the exposure values for cows' milk are modelled estimates, the exposure estimates for cows' milk should be refined in order to improve the accuracy of the risk characterisation.

Result

Conclusion i) There is a need for further information and/or testing.

The following information is required:

- information on the toxicokinetics of pentaBDPE with respect to cows' milk including uptake from milk into the infant;

- information on the relative toxicity to the liver of pentaBDPE in young (neonatal) and adult animals;

- further studies on potential effects on behaviour following neonatal dosing in order to determine the reproducibility of effects, the effects of repeated dosing and the significance of the effects to human development;

- exposure information from local and regional sources on the concentration of pentaBDPE in cows' milk.

However, following the agreement of the risk assessment conclusions reached on a technical basis, Member States noted the uncertainties expressed regarding the risk characterisation for infants exposed to pentaBDPE from human breast milk. They also noted the conclusion that further information would be required to remove these uncertainties and refine the risk assessment. Member States were concerned that it would take a significant time to gather the information and that the resulting refined risk assessment could then indicate a risk to breast-feeding infants. Furthermore, the bioaccumulative properties of the substance could cause concentrations in breast milk to rise while the data was being gathered. Consequently Member States agreed that risk reduction measures should be considered without delay for the sources of this exposure.

5.3 HUMAN HEALTH (PHYSICO-CHEMICAL PROPERTIES)

There are no risks from physico chemical properties arising out of the use of pentaBDPE.

Result

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

5.4 NOTE FOR ALL INFORMATION REQUIRED UNDER CONCLUSION (I)

A draft risk reduction strategy for pentaBDPE has been developed. This strategy proposes a restriction on the marketing and use of pentaBDPE under Directive 76/769/EEC. If this strategy is adopted, then the proposed testing requirements for pentaBPDE should be adjourned in the interests of animal welfare and cost vs. benefit unless expert advice is provided which indicates that tests may be relevant to the controls which emerge from negotiations under Directive 76/769/EEC.