

HIGH PRODUCTION VOLUME (HPV)
CHEMICALS CHALLENGE PROGRAM

TEST PLAN

For

DIPHENYLOXIDE

CAS NO. 101-84-8

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EXECUTIVE SUMMARY

Solutia Inc. and The Dow Chemical Company voluntarily submit the following screening information data and Test Plan covering the chemical, Diphenyl Oxide, also known as Diphenyl Ether and DPO (CAS No. 101-84-8), for review under the Environmental Protection Agency's High Production Volume (HPV) Chemicals Challenge Program.

A substantial amount of data exists to evaluate the potential hazards associated with DPO. Use of key studies or estimation models available from data already developed provide adequate support to characterize each Endpoint in the HPV Chemicals Challenge Program without the need for additional, unnecessary testing.

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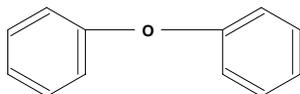
TEST PLAN FOR DIPHENYLOXIDE (DPO)

I. INTRODUCTION AND IDENTIFICATION OF CHEMICAL

Under EPA's High Production Volume (HPV) Chemicals Challenge Program, Solutia Inc. (Solutia) and The Dow Chemical Company (Dow) has committed to voluntarily compile basic screening data on Diphenyl Oxide or DPO. The data included in this Test Plan provide physicochemical properties, environmental fate, and human and environmental effects of DPO, as defined by the Organization for Economic Cooperation and Development (OECD). The information provided comes from existing data developed by or on behalf of Solutia or Dow or found in the published scientific literature and fulfills Solutia's and Dow's obligation to the HPV Challenge Program.

A. Structure and Nomenclature

Following is a structural characterization of DPO and associated nomenclature.



Diphenyl Oxide

CAS No. : 101-84-8

Synonyms: diphenyl ether; Benzene, 1,1'-oxybis-; DPO

B. Manufacturing & Use

DPO is manufactured by two US producers, Solutia and Dow; each operating a single manufacturing site. The manufacturing operations are closed, continuous processes. Only a few employees are involved in its manufacture at each site and have minimal potential for skin or airborne exposure, which occur chiefly during material transfer operations. Due to the acute hazards and occupational exposure limit of 1 ppm, specific manufacturing procedures and practices have been established to minimize the exposure potential to DPO.

Diphenyl oxide is sold primarily to industrial customers, both in the U.S. and in the rest of the world, for use either as a heat transfer fluid (blended with biphenyl) or as a chemically reacted intermediate in the production of flame retardants, surfactants, textile dye labeling and in coating applications. Both in DPO's use as a chemical intermediate

and as a heat transfer fluid, DPO is processed and utilized exclusively in closed systems. Occupational exposure during processing or use would primarily occur during material transfer or, in the unlikely event, that there is an unplanned event. Loss to the atmosphere or from non-POTW aqueous streams during manufacturing or processing is minimal. Hence, very limited occupational or environmental exposure is expected to occur.

II. TEST PLAN RATIONALE

The information obtained and included to support this Test Plan have come from either:

- 1) Internal studies conducted by/or for Solutia (or its predecessor Monsanto Co.),
- 2) Internal studies conducted by/or for Dow
- 3) Studies that have been extracted from the scientific literature either as primary references or as found in well-accepted, peer-reviewed reference books, or
- 4) Studies that were estimated using environmental models accepted by the US EPA (1999b) for such purposes.

This assessment includes information on physicochemical properties, environmental fate, and human and environmental effects associated with DPO. The data used to support this program include those Endpoints identified by the US EPA (1998); key studies have been identified for each data Endpoint and summarized in Robust Summary form and included in Section VI. of this Dossier.

All studies were reviewed and assessed for reliability according to standards specified by Klimisch *et al* (1997), as recommended by the US EPA (1999a). The following criteria were used for codification:

1. Valid without Restriction - Includes studies which comply with US EPA and/or OECD-accepted testing guidelines, which were conducted using Good Laboratory Practices (GLPs) and for which test parameters are complete and well documented,
2. Valid with Restrictions – Includes studies which were conducted according to national/international testing guidance and are well documented. May include studies conducted prior to establishment of testing standards or GLPs but meet the test parameters and data documentation of subsequent guidance; also includes studies with test parameters which are well documented and scientifically valid but vary slightly from current testing guidance. Also included were physical-chemical property data obtained from reference handbooks as well as environmental endpoint values obtained from an accepted method of estimation (i.e. EPIWIN).
3. Not Valid – Includes studies in which there are interferences in either the study design or results that provide scientific uncertainty or where documentation is insufficient.
4. Not Assignable – This designation not used in this Dossier.

Those studies receiving a Klimisch rating of 1 or 2 are considered adequate to support data assessment needs in this Dossier. Additional studies have been identified during our literature search on the referenced HPV endpoints but have not been summarized in this Dossier. The reader is referred to one additional data compendium, which also summarizes available data on the physical-chemical properties, ecotoxicity, environmental fate and health effects of diphenyl oxide. This is the European Chemical Bureau (ECB) IUCLID Dossier for Diphenyl Oxide (2000).

III. TEST PLAN SUMMARY AND CONCLUSIONS

Conclusion: All HPV Endpoints have been satisfied with data from studies that were either well documented, used OECD guideline methods and conducted in accord with GLPs, or were estimated from acceptable estimation modeling programs. Hence, no further testing for any of the HPV Endpoints is deemed necessary (Table 1).

Physical-chemical property values (Melting Point, Boiling Point, Vapor Pressure, and Water Solubility) were obtained from reputable, universally accepted reference guides. These endpoints have been classified as “2-Valid with restrictions”. The Partition Coefficient was measured using OECD Guideline 107 Method and estimated using an EPA recommended model; it has been classified as “1-Valid without restriction”.

Environmental Fate values for Transport (Fugacity) were obtained using a computer estimation –modeling programs (Fugacity Based Environmental Equilibrium Partitioning Model, Level I, 1999) and (EPIWIN Level III Fugacity Model, 2002), recommended by EPA; they have been classified as “2-Valid with restrictions”. Biodegradation data was obtained using methodology patterned after JAOCS 42:986 and JAOCS 45:432 and classified as “2-Valid with restrictions”. Photodegradation data was estimated using EPA recommended model and was considered “2-Valid with restrictions”. In keeping with OECD SIDS guidance, no testing for Stability in Water is planned with DPO as it is generally recognized as “stable” in aqueous solutions. Supplemental data to evaluate Bioaccumulation in fish used a protocol consistent with OECD Guidance and was considered “2-Valid with restrictions”.

Ecotoxicity Endpoints for Acute Invertebrate Toxicity and Acute Fish Toxicity were met with studies conducted with methodology that was consistent with OECD test guidance. The Acute Plant Toxicity study was conducted according to a regulatory-recommended study design. Studies supporting the Acute Invertebrate, Acute Fish Toxicity and Acute Toxicity to Plants Endpoints were designated a reliability level of “2-Valid with restrictions”.

Mammalian Toxicity Endpoints (Acute Toxicity, Repeated Dose Toxicity, Ames Mutagenicity and Chromosomal Aberration Testing, Developmental Toxicity and

Reproductive Toxicity) have all been filled by way of tests which either conformed directly with OECD test guidance or followed test designs similar to OECD guidance. The Acute Toxicity Endpoint was supported by a study, which was consistent with OECD guideline 401 and GLPs, and was considered “2- Valid with restrictions”. The Repeated Dose Toxicity Endpoint was conducted with methodology consistent with an OECD guideline 408 study in accordance with GLPs. It also was codified as “1- Valid without restriction”. The Ames test followed a study design equivalent to OECD guideline # 471 and the chromosomal aberration study was conducted under OECD guideline # 473 parameters. Thus, the Ames test was categorized as “2- Valid with restrictions” while the chromosomal aberration study was classified as “1- Valid without restrictions”

A Developmental Toxicity Study fulfills the HPV requirements for the Mammalian Toxicity Endpoint. This study was conducted to meet OECD Guideline 414 in design and is compliant with GLPs. It has been classified as “1- Valid without restriction”.

Based on previous guidance from EPA and the OECD SIDS program, the endpoint of Reproductive Toxicity has been adequately met by (a) histopathologic data reporting the absence of toxicologic effects for the male and female reproductive/endocrine organs examined in a recent GLP OECD 408 Subchronic Toxicity study, and (b) availability of a GLP OECD 414 Developmental Toxicity study.

A tabular depiction of data availability and testing recommendations for Diphenyl Oxide (DPO) can be found on the following page.

Table 1. Test Plan Matrix for Diphenyl Oxide

	Info. Avail.?	OECD?	GLP?	Other Study?	Estimat. Method?	Accept- Able ?	Testing Recomm.?
PHYSICAL CHEMICAL							
Melting Point	Y	R	N	N	-	Y	N
Boiling Point	Y	R	N	N	-	Y	N
Vapor Pressure	Y	R	N	N	-	Y	N
Partition Coefficient	Y	R	N	Y	-	Y	N
Water Solubility	Y	R	N	Y	-	Y	N
ENVIRONMENTAL FATE ENDPOINTS							
Photodegradation	Y	N	N	N	Y	Y	N
Biodegradation	Y	N	N	Y	-	S	-
Transport between Environmental Compartments (Fugacity)	Y	N	N	N	Y	Y	N
Bioaccumulation	Y	N	N	N	-	Y	N
ECOTOXICITY							
Acute Toxicity to Fish	Y	N	Y	Y	-	Y	N
Acute Toxicity to Aquatic Invertebrates	Y	N	Y	Y	-	Y	N
Acute Toxicity to Aquatic Plants	Y	N	Y	Y	-	Y	N
MAMMALIAN TOXICITY							
Acute Toxicity	Y	N	N	Y	-	Y	N
Repeated Dose Toxicity	Y	N	Y	Y	-	Y	N
Genetic Toxicity – Mutation (Ames)	Y	N	N	Y	-	Y	N
Genetic Toxicity – Chromosomal Aberrations	Y	Y	Y	N	-	Y	N
Developmental Toxicity	Y	Y	Y	N	-	Y	N
Reproductive Toxicity	Y	Y	Y	N	-	Y	N

Y = Yes; N = No; S = Supplemental, not required under HPV; R = Reputable Reference; - = Not applicable

IV. DATA SET SUMMARY AND EVALUATION

The key studies used in this assessment to fulfill the HPV requirements have been placed in an Endpoint-specific matrix, and further discussed below. Robust Summaries for each study referenced can be found in Section VI of this dossier.

A. Chemical/Physical Properties

Table 2. Selected Chemical/Physical Properties of Diphenyl Oxide

Chemical	Boiling Pt. (°C.)	Melting Pt.(° C.)	Vapor Pressure (hPa @ 20 °C)	Water Solubility (ppm)	Partition Coefficient (Log Kow)
Diphenyl Oxide CAS No. 101-84-8	257-259	28	2.67 Pa or 0.0267 hPa	21 @ 25 °C.	4.2

All HPV Endpoints for Chemical/Physical Properties have been completed with reliable information and taken from either primary or reputable textbook references (Table 2). The values, which are included in the Robust Summary section of this Dossier, have been classified as “2-Valid with restrictions”. Additional Chemical/Physical property values can also be found in the ECB IUCLID Dossier for DPO (2000).

In summary, these data indicate that DPO is a white crystalline solid or colorless liquid, depending upon temperature. The melting point of DPO is 28 °C. DPO is moderately soluble in water. The magnitude of the octanol:water partition coefficient indicates a moderate bioconcentration potential for DPO. However, the measured bioconcentration factor for diphenyl oxide in rainbow trout has been reported to be 196, indicating significant metabolic clearance of the compound from the fish.

Conclusion – Adequate reference values are available to provide needed information on the Physical-Chemical Properties associated with DPO. Therefore, no additional data development is needed for these HPV Endpoints.

B. Environmental Fate and Biodegradation

Extensive reviews and study citations in the Environmental studies area have been published on DPO, and are summarized in the ECB IUCLID Dossier (2000) for DPO. Key studies have been selected for this Dossier, which fairly depict the consensus conclusion/values for each of the HPV Endpoints listed (Table 3), and are summarized in the Robust Summary section of this Dossier. The Biodegradability study selected employs methodology that is well established for determination of this HPV Endpoint; it has been designated as “2-Valid with restrictions”. Photochemical degradation of DPO

was estimated using the Atmospheric Oxidation Program recommended for use by EPA. (AOP, 1997, Syracuse Research Corporation). Estimation of Transport (Fugacity) was made using an EPA-accepted estimation model (Fugacity Based Environmental Equilibrium Partitioning Model, Level I 1997) and (EPIWIN Level III Fugacity Model, 2002). These values have been designated as “2-Valid with restrictions”. No experimental data could be located to define the Stability in Water (Hydrolysis) of DPO, nor could a value be calculated using EPIWIN (2002), as this chemical has only aromatic and ether functional groups; both of these groupings are listed in Lyman et al (1990) as Generally Resistant to Hydrolysis. Thus, “[t]esting for Stability in Water is not needed for substances generally recognized to have molecular structures or possess only functional groups that are generally known to be resistant to hydrolysis “ (OECD, 2002). An overview of the known qualities of the environmental properties of DPO is provided below.

The environmental fate of DPO can be summarized as follows. Based on fugacity modeling, DPO released into the environment will partition primarily between air, water and soil (Table 3 - Fugacity). Upon release to the air, DPO will be degraded in the atmosphere by reaction with photochemically produced hydroxyl radicals. The estimated half-life in air is approximately 1 day (Table 3 – Photodegradation). DPO is expected to biodegrade in a wastewater treatment plant (Table 3 – Biodegradation). Substantial biodegradation of DPO in biochemical oxygen demand (BOD) tests (ECB IUCLID, 2000) indicates that, upon release to surface waters and soil, biodegradation of DPO will occur. DPO is not susceptible to hydrolysis. Based on the octanol/water partition coefficient, DPO has a moderate potential to bioconcentrate in aquatic species. However, the measured bioconcentration factor for diphenyl oxide in rainbow trout has been reported to be 196, indicating significant metabolic clearance of the compound from the fish.

Table 3. Environmental Fate and Biodegradation Parameters for Diphenyloxide

Chemical	Biodegradation Rate	Stability in Water	Fugacity (%) Level III	Photodegrad. Rate
DPO CAS No:101-84-8	51-94% primary biodegradation after 7 days in activated sludge	Stable	Air – 4.47 Water – 28.9 Soil – 63.7 Sediment – 2.87	50% after 1.1 day

Conclusion – Adequate studies following either OECD or EPA test guidance are available to provide needed information regarding the Biodegradation and Photodegradation of DPO. Information on Transport (Fugacity) was completed using the Fugacity Based Environmental Equilibrium Partitioning Model Level I and EPIWIN Level III Fugacity Model, accepted estimation-modeling programs. No additional data development is warranted for these HPV Endpoints.

C. Aquatic Toxicity

The aquatic toxicity of DPO has been extensively reviewed (ECB IUCLID, 2000) and contains numerous acute toxicity studies on algae, invertebrates and fish. The key studies selected for development of Robust Summaries are reported in Table 4 and depict the level of toxicity generally observed for these Endpoints within the overall dataset.

Both the Acute Invertebrate Toxicity and Acute Fish Toxicity were met with studies conducted with methodology that was consistent with OECD test guidance and under GLPs. The Acute Plant Toxicity study was conducted according to a regulatory-recommended study design under GLPs. Studies supporting the Acute Invertebrate, Acute Fish Toxicity and Acute Toxicity to Plants Endpoints were designated a reliability level of “2-Valid with restrictions”.

Table 4. Aquatic toxicity parameters for Diphenyl Oxide (DPO)

Chemical	Fish LC 50 (mg/L)	Invertebrate EC50 (mg/L)	Algae EC50 (mg/L)
Diphenyl Oxide CAS No.101-84-8	(rainbow trout -96 hr) 4.2	(Daphnia-48 hr) 1.7	(Selenastrum capricornutum 96-hrs) 2.5

DPO is considered to be only “moderately toxic”, according to EPA categorization guidance, toward these and other aquatic species following acute testing. Based on the pattern and release scenarios envisioned, DPO is expected to present a negligible risk to aquatic organisms.

Conclusion – Adequate studies which are consistent with internationally accepted test guidelines are available on all 3 Aquatic Toxicity Endpoints to assess the acute aquatic toxic hazards associated with DPO. Therefore, no additional data development is needed for these HPV Endpoints.

D. Mammalian Toxicity Endpoints

A summary of available toxicity data used to fulfill the HPV Endpoints for Mammalian Toxicity is found in Table 5. Each report has been further summarized in the Robust Summary section of this Dossier.

Table 5. Mammalian Toxicity of Diphenyl Oxide (DPO)

Chemical Name/ CAS no.	Acute Toxicity	Repeat Dose Toxicity	Reproductive Toxicity	Developmental Toxicity	Mutagenicity –In Vitro	
					Point Mutations (Ames)	Chrom. Aberr. (CHO cells)
Diphenyl oxide 101-84-8	Oral LD50 (rat) 2450 mg/kg	90-day (oral-rat) NOAEL >5000 ppm in diet	Histopathologic exam of male and female reproductive/ endocrine organs in subchronic OECD 408 study, and availability of OECD 414 study	(gavage-rat) NOAEL for Maternal toxicity 50 mg/kg bw NOAEL for developmental toxicity 500 mg/kg bw	Neg.- All strains (TA98, TA100, TA1535, TA1537) +/- S9	Neg. +/- S9

1.0 Acute Toxicity

An acute toxicity study by the oral route of exposure has been conducted as summarized in Table 5. This study was conducted prior to, but consistent with GLPs (finalized in 1979) and used a study design consistent with OECD Test Guidelines 401; it is considered “2- Valid with restrictions”. The acute rat oral toxicity study has been chosen as the key study to fulfill this HPV Endpoint.

DPO is considered to be of low toxicity after acute oral exposure to rats. Additional acute toxicity values in animals can be found listed in the compendium report cited above.

Conclusion – A quality study, consistent with OECD/GLP guidance, is available to assess the Acute hazards associated with DPO. Therefore, no additional data development is needed for the Acute Toxicity HPV Endpoint.

2.0 Repeated Dose Toxicity

DPO has been adequately tested by the oral route of exposure to define its Repeated Dose Toxicity. The key study used for this HPV assessment is cited in Table 5 and summarizes a 90-day subchronic rat study by the oral route reported in 1990. This study was conducted using a study design consistent with OECD Test Guideline 408, and under

GLP auspices and is considered “1- Valid without restriction”. Groups of 20 male and 20 female rats received diets containing concentrations of 0, 200, 1000 and 5000 ppm DPO for 13 weeks. Ten rats/sex/dose were terminated at the end of the 13-week dosing period. The remaining 10 rats/sex/dose were maintained on basal diet for a 4 week post-treatment group. A full complement of clinical parameters was evaluated. Histopathologic examination was conducted on a full complement of tissues, including the male and female reproductive and endocrine organs. Body Weight gain and Food Consumption were decreased in the 5000 ppm males and females and in the 1000 ppm females; these changes were secondarily attributed to the unpalatability of the DPO test diets, as evidenced by the increases in Body Weight and Food Consumption during the post-treatment period. No adverse toxicologic effects were attributed to the DPO, and the NOAEL was determined to be 5000 ppm in the diet, equating to 301 mg/kg/day for males and 335 mg/kg/day for females. A summary of this study is found in the Robust Summary section of this Dossier.

Conclusion - Thus, the Repeated Dose HPV Endpoint for DPO has been fulfilled with a 90-Day Subchronic study in rats deemed “1- Valid without restriction”. No further testing is needed for completion of information related to the Repeat Dose HPV Endpoint.

3.0 Mutagenicity and Chromosomal Aberrations

3.1 Mutagenicity Testing (Ames test)

DPO has been extensively tested in the standard Ames assay for point mutations (ECB IUCLID, 2000). DPO elicited no mutagenic response in any of the *S. Typhimurium* tester strains employed, either with or without inclusion of metabolic activation. A representative study has been summarized in the Robust Summary section of this Dossier and its results are referenced in Table 5. Its design and documentation are such that it is considered consistent with OECD guideline 471 and thus is “2- Valid with restrictions” for this assessment.

Thus, it is concluded that adequate testing of sufficient quality has been performed on DPO to evaluate the Ames Test (Point Mutation) HPV Endpoint; no further testing is needed for this Endpoint.

3.2 - Chromosomal Aberrations

DPO has been tested in an in vitro chromosomal aberration test; no significant increases in structural aberrations per cell at any treatment concentration were observed. A Robust Summary has been prepared for this study and its results are referenced in Table 5. It was conducted using GLPs and meets OECD guideline 473 parameters; it is considered “1-Valid without restriction”.

The HPV Chromosomal Aberration Endpoint for testing of DPO has been fulfilled with adequately conducted and documented studies and no further testing is needed.

4.0 Developmental Toxicity

A Developmental Toxicity study of DPO has been conducted using oral gavage (Table 5) and summarized in Dossier section VI - Robust Summaries. It was conducted under GLPs and meets OECD 414 Testing Guidelines. Based on general acknowledgement of its scientific and regulatory acceptability, it has been judged as "1- Valid without restriction" for purposes of this assessment. The test material was administered by oral gavage in corn oil to groups of 24 mated female rats at 0, 50, 200 and 500 mg/kg/d. Single oral daily dosages were administered at a volume of 5 ml/kg by gavage, on gestation days 6-15. Maternal toxicity was noted at the two higher dose levels of 500 and 200 mg/kg/day, and included decreases in Body Weight gain and Food Consumption, excessive salivation, alopecia and staining of the hair coat in the ano-genital region; deaths of 2 high dose rats were considered related to the treatment. No effects observed on fetal resorptions, fetal viability, postimplantation loss or total implantations. Mean litter weights in treated and control groups were similar. No significant increases were observed in incidence of fetal malformations or variations at any treatment level. The NOAEL for maternal toxicity was ≥ 50 mg/kg/d and the NOAEL for teratogenicity was ≥ 500 mg/kg/d, the highest dosage tested.

5.0 Reproductive Toxicity

The Reproductive Toxicity endpoint for DPO under the HPV program is considered adequately met by (a) availability of a recent comprehensive GLP OECD 408 subchronic toxicity study that included histopathologic examination that revealed no adverse effects on the male and female reproductive organs (including testes, epididymides, prostate, seminal vesicles, uterus, ovaries, vagina, mammary gland, pituitary, thyroid, parathyroid and adrenals, and (b) availability of a GLP Developmental Toxicity study (OECD 414). The EPA HPV Guidance Document entitled 'Determining the Adequacy of Data' cites the OECD SIDS position wherein if there is an existing, adequate 90-day repeat-dose study that demonstrates no effects on reproductive organs (particularly the testes), than a Developmental Toxicity study (e.g., OECD 414) can be considered as an adequate test for information on reproduction/developmental effects. These criteria have been adequately met by the data presently available on DPO.

In conclusion, the Reproductive Toxicity HPV Endpoint has been fulfilled with conduct of a Developmental rat study and a 13-week Subchronic Toxicity study which followed OECD testing guidance and was conducted under GLPs. As no effects on male or female gonads were observed in the Subchronic study, a combination of these two studies has been used to fulfill this HPV requirement, per US EPA HPV guidance. Thus, no further testing for this HPV Endpoint is required.

V. REFERENCES

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VI. ROBUST STUDY SUMMARIES -

IUCLID Data Sets are appended