

Safety Data Sheet

1. Chemical product and company identification

Chemical product name (product name) : DOP

Company name : Japan Plasticizer Industry Association

Address : Tobu Building, 5-26, Motoakasaka 1-chome, Minato Ward, Tokyo, Japan 107-0051

Department in charge : Japan Plasticizer Industry Association

Person in charge (prepared by) : Technical Department

Phone : 03-3404-4603

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Recommended use and limitations : Plasticizer and solvent for various resins

Reference number : 0001

2. Hazards identification

GHS category

Physical hazard statements	: Explosive	Not applicable
	: Flammable gases (including chemically unstable gas)	Not applicable
	: Aerosol	Not applicable
	: Oxidizing gases	Not applicable
	: Gases under pressure	Not applicable
	: Flammable liquids	Not classified
	: Flammable solids	Not applicable
	: Self-reactive substances	Not applicable
	: Pyrophoric liquids	Not classified
	: Pyrophoric solids	Not applicable
	: Self-heating substances	Classification not possible
	: Substances and mixtures which, in contact with water, emit flammable gases	Not applicable
	: Oxidizing liquids	Not applicable
	: Oxidizing solids	Not applicable
	: Organic peroxides	Not applicable
	: Corrosive to metals	Classification not possible
Health hazards	: Acute toxicity (oral)	Not classified
	: Acute toxicity (subcutaneous)	Not classified
	: Acute toxicity (inhalation: gas)	Not applicable
	: Acute toxicity (inhalation: vapor)	Classification not possible

possible

: Acute toxicity (inhalation: dust) Not applicable
 : Acute toxicity (inhalation: mist) Not classified
 : Skin corrosion/irritation Not classified
 : Serious eye danger/eye irritation Category 2B
 : Respiratory sensitization Classification not possible
 : Skin sensitization Not classified
 : Germ cell mutagenicity Not classified
 : Carcinogenicity Not classified
 : Reproductive toxicity Not classified
 : Specific target organ toxicity (single exposure) Classification not possible
 : Specific target organ toxicity (repeated exposure) Not classified
 : Aspiration hazard Classification not possible

Environmental hazards

: Hazardous to the aquatic environment (acute) Not classified
 : Hazardous to the aquatic environment (chronic) Not classified
 : Hazardous to the ozone layer Classification not possible

GHS label

Hazard pictogram

: None

Signal word

: Warning

Hazard statements

: Eye irritation

Precautionary statements

:

[Safety measures]

Obtain the SDS before use.

Do not handle until all safety precautions have been read and understood.

Wear personal protective equipment as needed.

Do not breathe the mist.

Use only outdoors or in a well-ventilated area.

Avoid releasing into the environment.

[First aid measures]

If in eyes, rinse cautiously with water for several minutes. Next, remove contact lenses, if present and easy to do. Continue rinsing.

If exposed or concerned, get medical advice/attention. Call a doctor if you feel unwell.

If inhaled, remove person to fresh air and keep comfortable for breathing.

Collect spillage.

[Storage]

Keep container tightly closed and store in a well-ventilated place.

[Disposal]

Commission disposition of the content/container to the dedicated waste disposer authorized by the prefectural governor.

3. Composition/information on ingredients

Discrimination of single substance or mixture	: Single substance
Chemical name	: Bis(2-ethylhexyl) phthalate
Generic name	: Di(2-ethylhexyl) phthalate (Abbr. DEHP)
Other name	: Dioctyl phthalate (Abbr. DOP) 1,2-Benzenedicarboxylic acid bis(2-ethylhexyl) ester
Chemical property (chemical formula)	: $C_6H_4(COOCH_2CH(C_2H_5)C_4H_9)_2$
CAS No.	: 117-81-7
Concentration or concentration range	: Not less than 99%
Reference number in gazette list in Japan	: (Chemical Substances Law, Industrial Safety and Health Law) (3)-1307

4. First-aid measures

If inhaled	: Remove person to fresh air and keep at rest immediately and get medical advice as needed.
If on skin	: Flush with running water and soap. If symptoms such as blisters and pain occur, get medical advice as needed.
If in eyes	: Rinse cautiously with water for several minutes. Next, remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention/advice.
If swallowed	: Get water to rinse out mouth. Get medical attention/advice if the person feels unwell.

5. Fire-fighting measures

Appropriate extinguishants	: Foam, powder and carbon dioxide gas are effective.
Extinguishants that should not be used	: No information.
Specific hazards regarding fire-fighting	: Irritating, toxic or corrosive gas may be generated according to the fire.
Specific fire extinguishing	: Perform fire-fighting having the wind at your back. Sprinkle the surrounded facilities with water for cooling.
Protection of the fire-fighting person	: Wear appropriate protective equipment (gloves and glasses or masks).

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	: When indoors, perform ventilation sufficiently by the end of disposition. In accidental release, prohibit the access of persons other than the interested party by stretching a rope around the surroundings. Take care of the place of accidental release because it is slippery.
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Environmental precautions	Wear protective equipment (see “8. Exposure controls/personal protection”) when working. : Take care so that the spill will not be discharged into rivers and affect the environment.
Collection/neutralization (Method and materials for containment and clean up)	: Stop accidental release. For a small spill, collect the spill by adsorbing it with absorbent (sawdust, soil, sand, or waste cloth) and wipe the residue well with waste cloth and dust cloths. For a large spill, prevent it from spreading by enclosing with noncombustible matter (such as soil) and collect it with a shovel or suction machine into an empty container.
Prevention of secondary disaster	: Remove all the fire sources quickly (prohibit nearby smoking, sparks and flames). Prevent inflows into drains, sewers, basements and closed places.

7. Handling and storage

Handling

Technical measure	: Take the actions for facilities described in “8. Exposure controls/personal protection” and wear protective equipment.
Local ventilation/general ventilation	: Perform the local ventilation and general ventilation described in “8. Exposure controls/personal protection.”
Precautions	: Prevent leakage, spills and projection and do not generate vapor for no reason. Keep away from high-temperature objects, sparks and flame and avoid contact with strong oxidants. Take countermeasures against static electricity and wear anti-static work clothes and shoes.
Precautions for safe handling	: Do not handle until all safety precautions have been read and understood. Watch out for fire. Do not contact, inhale or swallow. Avoid contact with eyes. Do not inhale mist or vapor. Wash your hands thoroughly after handling. Avoid releasing into the environment.
Avoidance of contact	: See “10. Stability and reactivity.”
Hygiene measure	: Rinse hands well after handling.
Storage	
Technical measures	: Provide the daylighting equipment , lighting and ventilation required for storage or handling of hazardous materials in the storage place.
Reactive hazardous substances	: See “10. Stability and reactivity.”
Storage condition	: Store away from oxidants. Store in a well-ventilated place.
Packaging material of container	: Use the container specified in the Fire Service Act.

8. Exposure controls/personal protection

Control level	: Not established.
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Permissible level	: ACGIH (2012 version) Japan Society for Occupational Health (2012 version)	TLV-TWA TLV-TWA	5 mg/m ³ 5 mg/m ³
Actions for facilities	: For using indoors, it is desirable to close the source or establish local ventilation equipment. Provide shower, hand-washing and eye-washing equipment and indicate the places clearly.		
Protective equipment			
Respirators	: Use gas masks for organic gas, air-supplied respirators, air respirators, etc. as the situation demands.		
Protective gloves	: Impermeable protective gloves		
Protective glasses	: Protective glasses with side panels (goggle type or full-face protective glasses as needed)		
Protective equipment for skin and body	: Antistatic long-sleeve protective clothes and shoes		

9. Physical and chemical properties

Appearance	: Colorless liquid		
Odor	: Almost odorless		
Threshold of odor	: No data available		
pH	: No data available		
Melting point/freezing point	: -50°C		
Boiling point	: 386°C		
Flash point	: 218°C (open)		
Evaporation rate	: No data available		
Flammable range	: Lower limit of explosion range 0.1 vol% (in the air) ¹⁾		
Vapor pressure	: 160 Pa (200°C) 6.7×10 ⁻³ Pa (68°C)		
Vapor density (air = 1)	: 13.46 (calculated value)		
Specific gravity	: 0.986 (20 / 20°C)		
Solubility	: Solubility in water: insoluble, 0.003 mg/L (25°C) : EU2001 ²⁾		
n-Octanol/water partition coefficient	: log Pow = 7.60 ²⁹⁾		
Spontaneous ignition temperature	: 400°C		
Decomposition temperature	: No data available		
Viscosity	: 77 mPa·s (20°C)		

10. Stability and reactivity

Reactivity	: Stable in usual handling and less reactive.		
Chemical stability	: Not self-degradable and chemically stable.		
Possibility of hazardous reactions	: Shows no self-reactivity and reacts with strong oxidants, strong acids and strong bases.		
Reactive hazardous substances	: Substance becoming the ignition source such as high temperature, flame, sparks, etc.		
Material to avoid	: Avoid blending with alkali metal hydroxides, acids, strong oxidants and nitrates.		

Hazardous degradation products : Generates carbon dioxide and carbon oxide by combustion.

11. Toxicological information

Acute toxicity : LD₅₀ (oral) Rat 30 g/Kg ³⁾
 LD₅₀ (oral) Rabbit 34 g/Kg ⁴⁾
 LD₅₀ (oral) Guinea pig 26 g/Kg ⁵⁾
 (Not classified)
 LD₅₀ (percutaneous) Rabbit 25 g/Kg ⁶⁾
 (Not classified)
 LD₅₀ (inhalation: vapor) No data available
 (Classification not possible)
 LD₅₀ (inhalation: mist) Rat >15.68 mg/L
 (Not classified)⁷⁾ (EU-RAR No.42(2003))

Skin corrosion/irritation : Rabbit 500 mg/24H Mild ⁸⁾

Considered not classified based on this test result.

Serious eye danger/eye irritation : Rabbit 500 mg/24H Mild ⁸⁾

According to ACGIH (7th, 2001),⁹⁾ ATSDR (2002),¹⁰⁾ EHC 131 (1992)¹¹⁾ and EU-ARA No.42 (2003), it is conceivable that DOP is not eye irritating or slightly eye irritating, and based on the study result that DOP is slightly eye irritating, it was classified into category 2B.

Respiratory sensitization : No data available. (Classification not possible)

Skin sensitization : According to the description in EU-RAR No. 42 (2003), DOP was not shown as skin sensitizing by test results of the “maximizing method and Buehler method using guinea pigs.” It was conceivable that DOP is not skin sensitizing, and it was classified as “not classified.”

Germ cell mutagenicity (mutagenicity) : DOP was negative from results of mutagenicity tests with microbes (not injurious to DNA).¹²⁾

According to CERI & NITE's Hazards Evaluation No. 7 (2004)¹³⁾ and ATSDR (2002),¹⁰⁾ DOP is positive in mutagenicity tests (dominant lethal tests) through generations. However, since administration routes in the tests showing positive were not appropriate and other dominant lethal tests and micronucleus tests proved negative, it was classified as “not classified.”

Carcinogenicity

: In 1980, it was reported that DOP administration at very high concentration to rats induced tumors in the liver. The subsequent research revealed that the hepatic tumors occur through a mechanism unique to rodents.¹⁴⁾¹⁵⁾ Based on this, in 2000, IARC (International Agency for Research on Cancer) modified the DOP carcinogenic classification from the conventional “2B” (possibly carcinogenic to humans) to “3” (not classifiable as to carcinogenicity for humans) because of no carcinogenicity in humans.¹²⁾¹⁶⁾ At the meeting in February 2011, however, IARC decided to return DOP to “2B.”³⁶⁾ It is not because new evidence in humans was found, but because further investigations and research are considered necessary for the mechanism and epidemiology of carcinogenicity in rodents. The Japan Plasticizer Industry Association (JPIA) examined in detail the articles used as the evidence for the modification,³⁷⁾⁻³⁹⁾ and considered as in the past that species differences exist in DOP carcinogenicity, and the GHS classification was established as “not classified.”

Reproductive toxicity

: The substance was administered to a pair of male and female mice by blending into food, and the pair mated multiple times. As a result administration of 144 mg/kg/day or more was observed to produce infertility and decrease the number of surviving babies of the same pair.^{17), 18)}

No influence is observed on testis in testing the substance by using adult and juvenile marmosets.^{14), 19), 20), 21)}

From the data of rats/marmosets in the studies performed so far, it was shown that a large species difference exists in the reproductive toxicity (including testoid toxicity) of DOP between rodents and primates, and applying the data obtained in rodents to humans is not considered. In the past literatures of the assessment in CSTEE in EU,²²⁾ assessment by CERHR in the U.S.A.²³⁾ and assessment by Advanced Industrial Science and Technology of Japan,²⁴⁾ it is observed that there is any species difference.

In the estimation of acceptable level based on the data of rodents, the discussion about the above species difference has not been reflected to the safety coefficient, and the possibility of reproductive toxicity in humans has not been concluded yet.

It has been reported in the aspect of metabolism of DEHP that there is a species difference between rodents and humans. That is, after ingestion of DEHP in rodents, its free metabolite is likely to circulate in the body, but in humans, most of the metabolites are excreted from the body quickly in the nontoxic glucuronide form.²⁵⁾ These phenomena have been confirmed in the experimental result of pharmacokinetics in the liver-humanized chimera mice, and the amount of exposure estimated from the humanized PBPK model and human biomonitoring data is incommensurably lower than the present TDI value.

That is, it was concluded that the risk is managed appropriately.²⁶⁾

In compliance with the present manual for GHS classification, the evaluation of species difference is insufficient, it is inappropriate for DOP with vast amounts of research data to perform the evaluation in humans as the evaluation of species differences is insufficient, and at present, it should not be classified (“not classified”).

Specific target organ toxicity, single exposure	: Cannot be classified because of lack of data.
Specific target organ toxicity, repeated exposure	: As described in the reproductive toxicity section, it was found from the data of the study in rats/marmosets performed so far that the pharmacokinetics of DOP is different between rodents and primates, and it is shown that testoid toxicity does not develop in primates. (Not classified)
Aspiration hazards	: No data available. (Classification not possible)
Others	: No activations were observed in estrogen activation tests in vivo (uterine hypertrophy reaction test with the ovariectomized rats). ^{27), 28)}

12. Ecological information

Biodegradability

Hazards to the aquatic environment (acute) : Acute toxicity has not been reported at concentrations up to water solubility (0.003 mg/L).

(Not classified)

(Reference)

Killifish LC₅₀ : 75 mg/L²⁹⁾

Salmon gairdneri LC₅₀ : 540 mg/L³⁰⁾

Hazardous to the aquatic environment (chronic) : Classified as “not classified” because of rapid degradation and low bioaccumulation.

The NOEL observed in the toxicity study of killifish in the initial growth stage by Shioda and Wakabayashi (2000)³¹⁾ and the Ministry of the Environment (2004d)³²⁾ using the dissolution aid by the method considered appropriate is far higher than water solubility, and the concentration is the implausible value at the DOP concentration detected in the general aquatic environment. ³³⁾

Persistence/degradation : Rapid degradation from the results of safety inspection on existing chemical substances (BOD solubility: 69%).³⁴⁾

Bioaccumulation : No or low concentrative property from the results (BCF=29.7) of safety inspection on existing chemical substances. ³⁵⁾

Migratory property in soil : No data available

Hazardous to the ozone layer : Classification not possible

13. Disposal consideration

Residual waste product

: Entrust disposition to the dedicated waste disposers licensed by prefectural governors.

If incinerating, spray into the fire chamber of incinerator with an exhaust gas washer and incinerate.

Take adequate care so that this substance will not be discharged into rivers, lakes and reservoirs, marine areas, sewage, etc.

Contaminated container/package : When disposing of empty containers, remove the content from the containers completely.
Do not drain waste water containing DOP before cleaning by disposition of activated sludge, etc.
Entrust disposition to the dedicated waste disposers licensed by prefectural governors.

14. Transport information

International regulation

UN class : Not applicable to the UN classification standard.

UN No. : None

National regulation

Land transportation : Load and transport in compliance with the standards of the Fire Service Act.

Special safety measures for transportation or transportation mode : When transporting by vehicles, it is desirable for freighters to deliver the precautions for transportation to the transporter.

In transportation, confirm that no leakage exists in the container, and load the containers so as to prevent falling, dropping and damage and to prevent cargo from collapsing.

15. Regulatory information

Labor Safety and Health Act : Article 57-1 of Act and Article 8-1 of Enforcement Ordinance, Attached Table 9: Hazards of which the name, etc. should be notified (Cabinet Order No. 481)

: Article 57-2 of the Act and Article 8-2 of the Enforcement Ordinance, Attached Table 9: Hazards of which the name, etc. should be notified (Cabinet Order No. 481)

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof : Paragraph 2, Article 2 of the Act, Article 1 of Enforcement Ordinance , Attached Table 1, class 1 designated chemical substance

Fire Service Act : Article 2 of the Act, Attached Table of hazardous materials, class 4 flammable liquids, class 4 petroleum (6,000 L)

Sea Water Protection Law : Enforcement Ordinance, Attached Table 1, Hazardous liquid substances (similar to class Y)

Food Sanitation Act : Specifications and standards of foods, additives, etc. 3-A-7 "In the devices or containers and packages contacting with foods containing oil or fat, the synthetic resin mainly containing polyvinyl chloride using bis(2-ethylhexyl) phthalate as a raw material should not be used as a raw material. However, this shall not apply when processed so that bis(2-ethylhexyl) phthalate may not dissolve or leach and may not be mixed with foods.

Specifications and standards of foods, additives, etc. 4-A-6 "the synthetic resin mainly containing polyvinyl chloride using bis(2-ethylhexyl) phthalate as a raw material should not be used as a raw material in toys."

Foreign Exchange and Foreign Trade Law : Because of being applicable to Item 16 of the attached table of Export Trade Control Order, referring to the guidelines of Ministry of Economy, Trade and Industry and prior consultation are desirable.

Revised Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. : Paragraph 5, Article 2 of the Act, priority assessment chemical substances

16. Other information

Where to inquire about the contents

Japan Plasticizer Industry Association Phone: 03-3403-4603, Fax: 03-3403-4604

Handling of the contents

The contents are prepared based on the materials, information and data available this time, but they do not guarantee the amount of content, physicochemical properties, risks/hazards, etc.

Since the precautions are for the usual handling, please use special handling after taking the safety measures appropriate for the method of use.

In actual handling and use, please see the SDS issued by the manufacturer of the product that you will use.

References

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- 6) Journal of Industrial Hygiene and Toxicology, 27, 130 (1945).
- 7) European Chemical Bureau, EU Risk Assessment Report, Vol.29 (2003).
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- 17) Koizumi, M. et al., "Recent study of the toxic effects of phthalate esters on reproduction and development," Japanese Journal of Food Chemistry and Safety, vol.7 (2), 65-71(2000)
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 - 22) Assessment by CSTE of EU
 - 23) Assessment by CERHR in the U.S.A.
 - 24) Assessment by National Institute of Advanced Industrial Science and Technology in Japan
 - 25) Kurata Y, Katoh M. et al., “Metabolite profiling and identification in human urine after single oral administration of DEHP”, *The Journal of Toxicological Sciences*, 37, 401- 414, 2012.
 - 26) Koichiro Adachi, Hiroshi Suemizu, Norie Murayama, Makiko Shimizu, Hiroshi Yamazaki, “Human biofluid concentrations of mono(2-ethylhexyl)phthalate extrapolated from pharmacokinetics in chimeric mice with humanized liver administered with di(2-ethylhexyl)phthalate and physiologically based pharmacokinetic modeling”, *Environmental Toxicology and Pharmacology*, 39, 1067-1073, (2015).
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Revision history

Dates revised	Reasons	Remarks
05/20/2001	Overhaul by the Japan Plasticizer Industry Association	
04/01/2002.	Additional description due to the revision of the Export Trade Control Order	
03/01/2005	Overhaul by the Japan Plasticizer Industry Association	
01/01/2007	Revision according to JIS Z 7250:2005 (corresponding to GHS)	
12/01/2008	Revision of classification in the Act for the Prevention of Marine Pollution and Maritime Disasters	
02/09/2009	Revision of octanol/water partition coefficient	
10/01/2009	Revision due to the PRTR law revision	
02/01/2010.	Revision due to the revision of the Ordinance on Industrial Safety and Hygiene	
04/01/2010	Revision according to the revised Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.	
08/06/2010	Revision according to JIS Z 7252:2009	
04/18/2011	Revision according to the revised Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.	
06/30/2011.	Revision associated with the change of classification of carcinogenicity in IARC	
02/28/2013.	Revision according to JIS Z 7253:2012	
03/24/2016	Revision due to the revision of Ordinance on Industrial Safety and Hygiene	