Safety Data Sheet SDS	Form No	SDS-MED-X-EN
	Issue Date	01.06.2013
MED-X BIS (2-ETHYHEXYL) PHTHALATE	Revision Date	12.06.2025
	Revision No	12

Prepared in accordance with the REACH Regulation (EC)1907/2006, CLP Regulation (EC) 1272/2008 and Regulation (EU) 2020/878

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Trade Name : MED-X

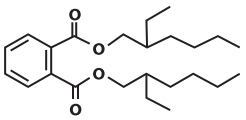
IUPAC Name : Bis-(2-ethylhexyl) phthalate

EC Number : 204-211-0

CAS Number : 117-81-7

Common Synonyms : DOP; DEHP; 1,2-benzene dicarboxylic acid; Di(2-ethylhexyl) phthalate; Di(isooctylphthalate); Phthalic Acid; Bis(2-ethylhexyl) ester; Dioctyl Ester

Molecular Structure :



Molecular Formula : $C_{24}H_{38}O_4$

Molecular Weight : 390,5

REACH Registration Number : 01-2119484611-38-0015

Chemical Structure : Mono-constituent substance-organic

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses Medical plasticizer.

1.3. Details of the supplier of the safety data sheet

Manufacturer **Plastay Kimya San. Tic. A.Ş.**
GGOSB İnönü Mah. Atatürk Bulv. No:22 Gebze /KOCAELİ – TURKEY 41400

Contact Person Melike ÖZKAN (Mrs.)-Chemical Assessment Specialist

1.4. Emergency telephone number

24 Hour Emergency Contact : 112

National Capital Poison Center : 114

Emergency Phone of the Company : +90 (262) 679 53 00 (08:30-18:00)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

According to the GHS/CLP guidelines- Regulation (EC) 1272/2008; Repr. 1B
(Reproductive Toxicity)
Route of exposure: Oral

2.2. Label elements

According to Regulation (EC) 1272/2008; Signal word: Danger
Hazard pictogram: GHS08: health hazard

Hazard statement
H360FD: May damage fertility. May damage the unborn child

Precautionary statements:
P201: Obtain special instructions before use.
P281: Use personal protective equipment as required.
P308+P313: If exposed or concerned: Get medical advice/attention: Get medical advice/attention.

2.3. Other hazards

No other effects. The substance does not meet the criteria for PBT or vPvB substance.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Name	EC No.	CAS No.	Content	Classification (EC 1272/2008)
bis(2-ethylhexyl) phthalate	204-211-0	117-81-7	>99,5 % (w/w)	Not classified

*Any impurities do not change the classification of DEHP as it is already classified as Repr.1B; H360FD

Composition Comments

- The data shown are in accordance with the latest EC Directives.

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Eye contact: Immediately flush eyes with water, while lifting the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

Skin contact: Remove contaminated clothing and shoes. Wash exposed area immediately with soap and water. Seek medical attention if irritation develops or persists. Wash clothing separately before reusing. Destroy or thoroughly clean contaminated shoes.

Inhalation: Remove victims to fresh air and keep at rest in a comfortable position for breathing. If not breathing, if breathing is regular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. Seek immediate medical attention If unconscious, place in recovery position and seek medical attention. Maintain an open airway.

Ingestion: Rinse the mouth of a person with plenty of water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Seek medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Inhalation : Material has low vapor pressure, so exposure to vapor is not likely. Exposure to dioctyl phthalate occurs from spray or mist, rather than from the vapor, unless heat is applied. If the product is heated, misted, or sprayed, it may cause irritation of the respiratory tract if inhaled.

Ingestion : May cause gastrointestinal irritation with nausea, vomiting and diarrhea. May cause central nervous system depression.

Skin contact : May cause mild skin irritation.

Eye contact : May cause mild eye irritation. Causes redness and pain.

Chronic effects : DEHP toxicity appears to be a high-dose phenomenon readily demonstrable in some but not all rodent species and strains. Liver toxicity, so characteristic of rodent responses to DEHP, appears to be irrelevant to humans.May impair fertility. May cause harm to the unborn child. DEHP has not been found to induce skin or respiratory sensitization in animals. Absorption rate of DEHP through the skin: 5%

4.3. Indication of any immediate medical attention and special treatment needed.

Avoid contact with this product while helping the person; keep the person warm. Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media: Compatible with dry chemical, water spray, carbon dioxide and polyvalent foam.

Unsuitable Extinguishing Media: No information available.

Special Hazard Arising from the Chemical: May produce acrid smoke and fumes if burning.

Special Protective Equipment for Fire-Fighters: Use self-contained breathing apparatus (SCBA) operated in positive pressure mode and complete protective clothing.

5.2. Special hazards arising from the substance or mixture.

Exposure Hazards: As an organic substance DEHP is combustible. Vapors may be heavier than air. They can spread along the ground and collect in low or confined areas. Running off from fire control or dilution water may cause pollution. Use water-spray to cool fire exposed containers. Preventing entry into sewers and water courses of the waste resulted from fire.

Specific hazards

Carbon monoxide (CO). Carbon dioxide (CO_2).

5.3. Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

Special Precautions for Fire-Fighters: Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer, or drain.

Protection of Fire-Fighters: Fire-fighters should wear appropriate protective equipment and self contained breathing apparatus. (SCBA) with a full face-piece operated in positive pressure mode. Clothing for firefighters (including helmets, protective boots, and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment, and emergency procedures

Keep unnecessary and unprotected personnel away from entering. Avoid contact with skin, eyes, and clothing-wear suitable protective equipment (see section 8). Do not touch or walk through spilt material. Shut off all ignition sources. Ventilate area of leak or spill. Personnels performing clean-up work should wear personal protective equipment and a self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode. Remove all sources of ignition.

6.2. Environmental precautions

Do not let product enter drains.

Avoid dispersal of spilt material contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil, or air). Contain and recover liquid when possible. Keep closed containers and dispose of all applicable federal, state, or local environment regulations.

6.3. Methods and material for containment and cleaning up

Methods of Cleaning Up: Absorb spills with dry sand, similar non-combustible absorbent material then place into suitable containers for later disposal. For large, dike and pump into suitable containers for disposal. Flush area with plenty of water. Wastewater will be treated in biological treatment plants.

Special Precautions: Do not use combustible materials, such as saw dust. Do not flush to sewer.

6.4. Reference to other sections

For personal protection, see section 8.

For waste disposal, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Protective Measures: Protect containers from physical damage. The personnel who handling the product must wear protective equipment. Sources of ignition such as smoking and open flames prohibited where DEHP is handled.

Hygiene Measures: Wash hands thoroughly after handling. Do not eat, drink, or smoke when using this product. Wash hands before eating, drinking, smoking, or going to the toilet. Take off all contaminated clothing and wash before reusing.

7.2. Conditions for safe storage, including any incompatibility.

Conditions for Safe Storage: Keep only in the original container, in a cool, dry, well-ventilated place. Keep away from food. Store locked up. Keep out of reach of children. Avoid static electricity by grounding.

Incompatible Products: Strong oxidants, acids, and alkalis

Incompatible Materials for Storage: PVC storage containers.

7.3. Specific end use(s)

The identified uses for this product are detailed in Section 1.2.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Exposure Pattern	DNEL	
	Workers	General Population
Long-term–inhalation, systemic	23.2 mg/m^3	6.86 mg/m^3
Long-term– dermal, systemic	6.58 mg/kg/day	3.95 mg/kg/day
Long-term– oral, systemic	Not Relevant	3.95 mg/kg/day

Exposure Limit Values

Occupational Exposure Limit (OEL):

Workplace exposure limit (Long-term exposure limit (8-hour TWA reference period)); 5 mg.m-3

Short-term exposure limit (STEL), 15 min:

Workplace exposure limit (Short-term exposure limit (15-minute reference period); 10 mg.m^{-3}

DNEL Values:

Long-term – inhalation, systemic: 4.5 mg/m^3

Long-term – dermal, systemic: 9.6 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Environmental Compartment	Value
Fresh water	0,00008 mg/l
Marine water	0,000008 mg/l
Aqua Intermittent	0,000014 mg/l
Fresh water sediment	1,8 mg/kg
Sewage treatment plant	1,0 mg/l
Soil	0,0132 mg/l
Marine sediment	0,18 mg/kg

8.2. Exposure controls

8.2.1. Appropriate Engineering Controls

Good general ventilation (typically ten air changes per hour) should be used. Ventilation rates should be matched to conditions. Supplementary local exhaust ventilation, closed systems, or respiratory and eye protection may be needed in special circumstances; such as poorly ventilated spaces, heating, evaporation of liquids from large surfaces, spraying of mists, mechanical generation of dusts, drying of solids, etc. Local exhaust ventilation is preferred because it can control the emission of the contaminant at its sources, preventing dispersions of it into the general work area. It is recommended safety showers and eye baths are available near the work side.

Protective equipment

Eye/Face Protection: It must be good industrial hygiene practice to minimize eye contact. Use chemical safety goggles and/or full-face shield where splashing is possible. Maintain eye wash and quick-drench facilities in the work area.

Hand Protection: Chemical resistant, impervious gloves complying with an approved standard should be always worn when handling chemical products.

Skin/Body Protection: Protective gloves of rubber, nitrilic rubber, or neoprene and protective clothing.

Respiratory Protection: For emergencies or instances where the exposure level are not known, there must be half face respirator for organic vapors. In cases of high potential exposure use a supplied-air respirator, full facepiece, operated in positive-pressure mode. **Respirator Type:** Air purifying respirator with an appropriate government approved (where applicable), air-purifying filter, cartridge, or canister.

Hygiene Measures: Do not eat, drink, or smoke while using this product. Wash hands before eating, drinking, smoking, or going to the toilet. Take off all contaminated clothing and wash before reusing.

Thermal Hazards: The substance does not represent a thermal hazard; thus special consideration is not required.

Other Precautions: Maintain shower, eye wash fountain and quick-drench facilities in work area.

Environmental Exposure Controls

Please act in accordance with local and national laws.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

PROPERTY	TEST METHOD	VALUE
Appearance	-	Transparent
Color (Pt/Co)	ASTM D 1209	Max.20
Odor	-	Typical
Water Solubility (20 °C, mg/L)	-	0,003
Acidity (mg KOH/g)	ASTM D 1045	Max.0,04
Boiling Point (°C)	-	~385
Freezing Point (°C)	-	~-45°C
pH-Value	-	Not available.
Flash Point (°C)	ASTM D 1310	Min.205 °C
Water Content (%)	ASTM 1364-02	≤ 0,03
Density (20 °C, g/cm^3)	ASTM D 1045	0.980-0.984
Viscosity (20 °C, cP)	ASTM D 1045	76-84
Flammability	-	Not available
Vapor Pressure (20°C, Pa)	-	~3,4.10^{-5}
Partition Coefficient (n-octanol/water)	Sparc Calculation Model	7,5
Refractive Index (20°C)	ASTM D 1045	1,4825-1,4865
Purity (%)	GC-Home Method	≥ 99,5
Autoignition Temperature (°C)	DIN 51794	~400
Oxidizing Properties	-	Not available

9.2. Other information

No information required.

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

No specific reactivity hazards are associated with this product.

10.2. Chemical stability

Stable under normal temperature conditions and recommended use. Stable under the prescribed storage conditions.

10.3. Possibility of hazardous reactions

Strong oxidizers, strong bases.

10.4. Conditions to avoid

Heat, flame, sources of ignition and incompatibles.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Carbon monoxide and dioxide may form and produce irritating fumes when heated to decomposition. - No data available in the event of fire: see section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity

	Dose	Species	Result
Acute Toxicity	LD50 (oral)	Rat- male and female	> 20000 mg/kg bw
	LD50 (dermal)	Rabbit	19800 mg/kg bw)
	LC50 (inhalation)	Rat	>10620 mg/kg bw)

- ***Repeated Dose Toxicity, oral***

NOAEL: 500 ppm (rat, male/female)

NOAEL (Rat, in feed, male): 28.9 mg/kg bw/day

NOAEL (Rat, in feed, female): 36.1 mg/kg/day

- ***Repeated Dose Toxicity, dermal***

LOAEL (Rat, male/female): 30.8 mg/kg bw/day

- ***Repeated Dose Toxicity, Inhalation***

NOAEC (Rat, male and female): 50 mg/m^3 air

Skin corrosion/irritation

Not classified based on available information.

Product: Species: Rabbit
Exposure time: 24 h
Result: Slightly.

Serious eye damage/eye irritation

Not classified based on available information.

Product: Species:
Rabbit Result: None
Remarks: No data available
According to the skin and eye irritation assays, DEHP is not corrosive.

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Germ cell mutagenicity
The substance was not mutagenic in bacteria. The substance was not mutagenic in mammalian cell culture. The substance was not genotoxic in mammalian cell culture.

Carcinogenicity
According to the criteria indicated in REGULATION (EC) No 1272/2008, no classification is warranted for carcinogenicity.

Product:
Remarks: This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.

Reproductive toxicity
For developmental effects, the NOAEL is 100 ppm (4.8 mg/kg bw/d) and the LOAEL is 1000 ppm (14 mg/kg bw/d), based on effects on the male reproductive organs.
According to Regulation (EC) No 1272/2008 Reproductive toxicity cat. 1B; H360FD: May damage fertility. May damage the unborn child.

STOT-single exposure
Not classified based on available information.

Product:
Remarks: No data available

STOT-repeated exposure
Not classified based on available information.

Product:
Remarks: No data available

Aspiration toxicity
Not classified based on available information.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

12.1. Ecotoxicity

The very low water solubility of DEHP causes problems when testing toxicity to aquatic organisms and when interpreting the results. Most aquatic studies with DEHP have been made at test levels, which exceed the water solubility of 3 µg/l.

12.1.1 Short-term toxicity to fish

Method: Brachy danio rerio (new name: Danio rerio); freshwater; semi-static, equivalent, or like OECD Guideline 203 (Fish, Acute Toxicity Test)

Prepared in accordance with the REACH Regulation (EC)1907/2006, CLP Regulation (EC) 1272/2008 and Regulation (EU) 2015/830

Results: LC0 (96 h): > 100 mg/L test mat. (nominal) NOEC (96 h): 100 mg/L test mat. (nominal)

Results of short-term studies show DEHP has no acute effect on fish at concentrations far exceeding its water solubility.

12.1.2 Long-term toxicity to fish

Method: Oryzias latipes; freshwater; semi-static

Results: NOEC (90 d): 5000 µg/L test mat. (nominal) based on total length and wet weight.

NOEC (90 d): 5000 µg/L test mat. (nominal) based on gonadal histology.

Results of long -term studies show that DEHP will not produce chronic toxicity to fish.

12.1.3 Short-term toxicity to aquatic invertebrates

Method: *Daphnia magna*; freshwater; static; equivalent or like OECD Guideline 202 (Daphnia sp. Acute Immobilization Test)

Results: EC50 (48 h): > 0.003 mg/L test mat. (estimated) based on: mobility.

Results of short-term studies show that DEHP has no acute effect on aquatic invertebrates at concentrations far exceeding its water solubility.

12.1.4. Long-term toxicity to aquatic invertebrates

Method: *Daphnia magna*; freshwater; static; OECD Guideline 211 (Daphnia manga Reproduction Test)
Results: NOEC (21 d): 0.158 mg/L test mat. (meas. (not specified)) based on: reproduction (and mortality) LOEC (21 d): 0.811 mg/L test mat. (nominal) based on: reproduction (and mortality)

As conclusion, considering all available data no value could be set to use as NOEC for aquatic invertebrates. Therefore, it is impossible to determine whether any effects observed in the toxicity tests may be relevant to use for derivation of a PNEC for water.

12.1.5 Algae and aquatic plants
EC50 (72 h): > 0.003 mg/L test mat. based on biomass
EC10 (72 h): > 0.003 mg/L test mat. based on biomass
In realistic environmental conditions sediment organisms will not be adversely affected by DEHP.

12.1.6 Toxicity to soil macro-organisms
DEHP showed no acute toxicity to earthworms at the limit concentration of 1000 mg/kg (dw) This NOEC cannot be normalized since the organic contents of the test soil was not reported.

12.1.7 Toxicity to terrestrial plants
Studies although (i) the test soil concentration was unclear, (ii) the effect concentrations in water were far above the solubility level, and (iii) exposure via the air is very unlikely considering the vapor pressure of DEHP in environmental conditions, these results support the result from Diefenbach where DEHP is not harmful to plants.

12.2. Persistence and degradability

Product:

Biodegradability: Result; Readily biodegradable.

Biodegradation: 82%

Prepared in accordance with the REACH Regulation (EC)1907/2006, CLP Regulation (EC) 1272/2008 and Regulation (EU) 2015/830

Exposure time: 29 d

Method: Ready Biodegradability: CO2 Evolution Test

12.3. Bio accumulative potential

DEHP is not bioaccumulated either by plants nor by soil organisms. Based on this result, it is considered that DEHP has a low potential for bioaccumulation.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This product does not contain any PBT or vPvB substances.

12.6. Other adverse effects

No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste and residues in accordance with local authority requirements. Avoid dispersal of spilt material and contact with soil, waterways, drains.

13.2.Contaminated Packaging:

The empty containers, tank cars and tank trucks are treated with steam and rinsed with plenty of hot water. The resulting effluents are treated in the same way as waste. The empty and clean containers are to be reused in conformity with regulations. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues.

SECTION 14: TRANSPORT INFORMATION

General

The product is not covered by international regulation on the transport of dangerous goods. (IMDG, IATA, ADR/RID).

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Transport Labels

No transport warning sign is required.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally Hazardous Substance/Marine Pollutant

No.

14.6. Special precautions for users

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health, and environmental regulations/legislation specific for the substance or mixture

REACH - Candidate List of Substances of Very High Concern for Authorization (Article 59): Not applicable.

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable.

Regulation (EC) No 850/2004 on persistent organic pollutants: Not applicable.

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances: Not applicable.

15.2. Chemical Safety Assessment

No chemical safety assessment has been carried out.

European union/EEA: In the event of purchase from an Arkema legal entity based in the European Economic Area (EEA), it is established that this product complies with the registration provisions of REACH Regulation (EC) No. 1907/2006, given that all of its components are excluded, exempted and / or registered. If purchasing from a legal entity established outside the EEA, please contact your local representative for more information.

TSCA (USA): The components of this product are all on the TSCA Inventory.
DSL/NDSL (CA): All components of this product are on the Canadian DSL.
IECSC (CN): All components of this product are listed or exempted.
ENCS (JP): All components of this product are listed or exempted.
ISHL (JP): Not all components of this product are listed or exempted.
KECI (KR): All components of this product are listed or exempted.
PICCS (PH): All components of this product are listed or exempted.
NZIOC (NZ): All components of this product are listed or exempted.
AIIC (AU): All components of this product are listed or exempted.
TCSI (TW): All components of this product are listed or exempted.

SECTION 16: OTHER INFORMATION

Abbreviations and acronyms used in the safety data sheet.

REACH: Registration, Evaluation, Authorization and Restriction of Chemical substances
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways. RID: International Carriage of Dangerous Goods by Road
IATA: International Air Transport Association.
ICAO-TI: Technical Instructions for the Safe Transport of Dangerous Goods by Air.
IMDG: International Maritime Dangerous Goods Code.
CAS: Chemical Abstracts Service.
ATE: Acute Toxicity Estimate.
LC_{50}: Lethal Concentration to 50 % of a test population.
LD_{50}: "Lethal Dose, 50%" or median lethal dose.
EC_{50}: 50% of maximal Effective Concentration.
EC_{50}: 50% of maximal Effective Concentration.

PBT: Persistent, bio accumulative and toxic
vPvB: Very Persistent and Very Bio accumulative.
DNEL: Derived No Effect Level
PNEC: Predicted No-Effect Concentration NOAEL:
No observable adverse effect level NOEC: No
Observed Effect Concentration Cat: Category
N.D.A: no data available
EU: The European Union

Revision Comments
Revised according to CLP Regulation.

Issued By

Melike ÖZKAN / **Chemical Engineer-Chemical Assessment Specialist**
E-Mail: melike.ozkan@plastay.com
Phone: +90 530 548 0420
Proficiency Certificate Date/No: 06.08.2022 / KDU01.23.02