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Safety Data Sheet (SDS)

SECTION 1: Identification of the substance/mixture and of the company /undertaking

1.1. Product identifier

Product name : PIA

Substance name : Isophthalic acid

EC No.: 204-506-4

CAS No.: 121-91-5

REACH Registration No. : 01-2119488938-12-0010

UFI Code : Not available

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

1) Relevant identified uses :

Formulation - Industrial manufacture of polymers
- Industrial use as an intermediate
- Industrial distribution of terephthalic acid

2) Uses advised against : Prohibition of use other than recommended use

3) Reason why uses advised against : Not available

1.3. Details of the supplier of the safety data sheet

1) OR(Only representative)

- Supplier name : REACHLAW
- Street address/P.O. Box : Vänrikinkuja 3 JK 21 FI-02600 Espoo, FINLAND
- Country ID/Postcode/Place : 246, 02600, Espoo
- Telephone number (if possible, indicate telefax) : +358 (0) 9 412 3055 / Fax +358 (0) 9 412 3049
- E-mail address of competent person responsible for the SDS : sales@reachlaw.fi
- National contact : +358 (0) 9 412 3055

2) Manufacturer

- Supplier name : LOTTE Chemical Corporation
- Street address/P.O. Box : 14F-16F, Lotte World Tower, 300 Olympic-ro, Songpa-gu, Seoul, Republic of Korea (05551)
- Country ID/Postcode/Place : 05551, Seoul
- Telephone number (if possible, indicate telefax) :
  Basic Materials +82-2-829-4114
  Advanced Materials +82-31-596-3114
- E-mail address of competent person responsible for the SDS : -
- National contact : Basic Materials +82-2-829-4114
  Advanced Materials +82-31-596-3114

1.4. Emergency telephone number :

- Opening hours : -
- Other comments (e.g. language(s) of the phone service) : +358 (0) 9 412 3055

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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No 1272/2008 (CLP) :

1) Physical-chemical Hazards : Not classified

2) Health Hazards : Not classified

3) Environmental Hazards : Not classified

2.1.2 Additional information: For full text of Hazard- and EU Hazard-statements: see SECTION 16

2.2. Label elements

2.2.1 Labelling according to Regulation (EC) No 1272/2008 [CLP] :

1) Hazard pictograms : Not applicable

2) Signal Word : Not applicable

3) Hazard Statements : Not applicable

4) Precautionary Statements

■ Prevention : Not applicable

■ Response : Not applicable

■ Storage : Not applicable

■ Disposal : Not applicable

5) Supplemental Hazard information (EU) : Not applicable

2.3. Other hazards :

- According to Annex XIII, the substance does not meet PBT or vPvB criteria.
- According to Regulation(EU) 2017/2100 and 2018/605, the substance does not affect to endocrine system.
- The substance is not listed in Article 59

SECTION 3: Composition/information on ingredients

3.1 Substances

Substance Name	CAS No. EC No.	Classification	SCL / M-factor / ATE	% [Weight]
Isophthalic acid	121-91-5 204-506-4	-	ATE (oral): > 5,000 mg/kg ATE (dermal): > 2,000 mg/kg ATE (inhalation, dust): (4 h): > 11,370 mg/㎥	100

SECTION 4: First aid measures

4.1. Description of first aid measures

4.1.1 General information :

- Where there is potential for exposure: restrict access to authorized persons; provide specific activity training to operators to minimize exposures.
- Take care to self-protect by avoiding becoming contaminated.
- Use adequate respiratory protection.
- Move contaminated patient(s) out of the dangerous area.
- Seek medical assistance - show the material safety data sheet or label if possible.

4.1.2. Following inhalation :

- Move to fresh air.
- Do not leave the victim unattended.
- Keep patient warm and at rest.
- Seek immediate medical attention.

4.1.3. Following skin contact :

- Take off all contaminated clothing and shoes.
- Immediately flush affected area with plenty of soap and water – continue for at least 15 minutes.
- If there are signs of irritation or other symptoms seek medical attention.

4.1.4. Following eye contact :

- Remove any contact lenses.
- Flush eyes with water thoroughly and continuously for at least 15 minutes.
- Keep eye wide open while rinsing.
- Protect unharmed eye.

4.1.5. Following ingestion :

- Clean mouth with water and drink afterwards plenty of water.
- Never give anything by mouth to an unconscious person.
- Seek medical attention if discomfort occurs.

4.1.6. Self-protection of the first aider

- Exposures require specialized first aid with contact and medical follow-up.
- Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

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

4.2.1. Over-exposure signs/symptoms : Not available

4.2.2. Potential acute health effects : Not available

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

4.3.1. Notes for the doctor : Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

4.3.2. Special treatment : No specific treatment.

SECTION 5: Firefighting measures

5.1. Extinguishing media

5.1.1. Suitable extinguishing media : Water spray, Dry chemical, Carbon dioxide

5.1.2. Unsuitable extinguishing media : Direct water jet.

5.2. Special hazards arising from the substance or mixture

- Non-flammable, the material itself does not burn, but it can decompose when heated to generate corrosive/toxic fumes.
- Dust may form explosive mixture in air when dispersed in a confined space
- The ignition of a sufficient concentration of a combustible dust in air in an unconfined space may result in a fireball and explosion.

5.3. Advice for firefighters

- This material, in its finely divided form, presents an explosion hazard when dispersed in a confined or unconfined area in a sufficient concentration and ignited in air.
- Ignition of a dust cloud in an unconfined area may result in a fireball.
- Ignition of a dust cloud in a confined space may result in a pressure buildup in equipment.
- Rescuers should put on appropriate protective gear.
- Evacuate area and fight fire from a safe distance.
- Dig a hole and confine the material for not to disperse for the disposal of fire fighting water.
- Move containers from fire area if you can do it without risk.
- Fire Involving Tanks, ALWAYS stay away from tanks engulfed in fire.
- Fire Involving Tanks, Cool containers with flooding quantities of water until well after fire is out.
- Fire Involving Tanks, Withdraw immediately in case of rising sound from venting safety devices or discoloration of tank.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel :

1) Protective equipment : Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Wear personal protective equipment.

2) Emergency procedures : Please note that materials and conditions to be avoided.
Avoid breathing vapours or mist.
Ensure adequate ventilation and absence of sources of ignition.

6.1.2 For emergency responders

- ELIMINATE all ignition sources (no smoking, flares, sparks or flames) from immediate area.
- Beware of accumulation of vapours in low areas or contained areas, where explosive concentrations may occur.

6.2. Environmental precautions :

- If material is released to the environment, take immediate steps to stop and contain release.
- Prevent or minimize formation of a dust cloud or layer.
- Eliminate all sources of ignition.
- Isolate hazard area and deny entry.
- Caution should be exercised regarding personnel safety and exposure to the released material.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment :

- Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container.
- Use a suitable airtight container for throw away.
- Use a dust collector and vacuum cleaner for cleaning.
- Minimize contact of spilled material with soils to prevent runoff to surface waterways.

6.3.2 For cleaning up

- Use a vacuum equipped with a High Efficiency Particulate Aerosol (HEPA) filter.
- Avoid creating dusty conditions and prevent wind dispersal.
- Prevent or minimize formation of a dust cloud or layer during cleanup.

6.3.3 Other information :

- Keep in suitable, closed containers for disposal.

6.4. Reference to other sections :

- Section 8 (protective equipment), section 13 (disposal instructions)

SECTION 7: Handling and storage

7.1. Precautions for safe handling

7.1.1. Protective measures :

- Use care in handling/storage.
- Please work with reference to engineering controls and personal protective equipment.
- Use a dust collector or hood
- Ground and bond lines and equipment used during transfer to reduce the possibility of

static spark-initiated fire or explosion. When airborne dust or a dust cloud is present, do not cut, grind, drill, weld or reuse containers unless adequate precautions are taken against these hazards.

7.1.2. Measures to prevent fire:

- This material, in its finely divided form, presents an explosion hazard when dispersed in a confined or unconfined area in a sufficient concentration and ignited in air.

7.1.3. Measures to prevent aerosol and dust generation:

- Ignition of a dust cloud in an unconfined area may result in a fireball.
- Ignition of a dust cloud in a confined space may result in a pressure buildup in equipment.

7.1.4. Measures to protect the environment: Not available

7.1.5. Advice on general occupational hygiene :

- Facilities using this material should assess their potential for combustible dust and static spark hazards and follow applicable federal, state and local laws and regulations and accepted codes and standards.
- When using, do not eat, drink or smoke.
- Wash thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities :

7.2.1. Technical measures and storage conditions :

- Be careful high temperature, high humidity conditions. Store in a well-ventilated area.
- Do not store on moist ground.

7.2.2. Packaging materials : Not available

7.2.3. Requirements for storage rooms and vessels :

- Store in tightly closed containers in a cool, dry, isolated, well-ventilated area away from heat, sources of ignition and incompatibles.

7.2.4. Further information on storage conditions :

- For large spills and releases follow the handling and storage recommendations as detailed in NFPA 654, NFPA 499 and NFPA 77 or similar guidance for your country or region.
- Avoid contact with strong oxidizers.
- Storage temperature : Ambient (Industrial).

7.3. Specific end use(s)

7.3.1 Recommendations : Not available

7.3.2 Industrial sector specific solutions : Not available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 Occupational exposure limits :

Chemical Name	ACGIH	Biological limit values	Exposure limits at intended use
Isoprene	Not applicable	Not applicable	Not applicable

8.1.2 DNELs/PNECs

DNELs								
	Workers				Consumers			
Route of exposure	Acute effect local	Acute effects systemic	Chronic effects local	Chronic effects systemic	Acute effects local	Acute effects systemic	Chronic effects local	Chronic effects systemic
Oral	Not required				No hazard identified	No hazard identified	No hazard identified	DNEL = 1.3 mg/kg
Inhalation	No hazard identified	No hazard identified	No hazard identified	DNEL = 8.8 mg/m³	No hazard identified	No hazard identified	No hazard identified	DNEL = 2.2 mg/m³
Dermal	No hazard identified	No hazard identified	No hazard identified	DNEL = 25 mg/kg	No hazard identified	No hazard identified	No hazard identified	DNEL = 12.5 mg/kg

PNECs	
Environmental protection target	PNEC
Fresh water	PNEC aqua (freshwater): 0.907mg/L Intermittent releases: 9.07mg/L
Freshwater sediments	PNEC sediment (freshwater): 1.246mg/kg dw
Marine water	PNEC aqua (marine water): 0.0907mg/L
Marine sediments	-
Food chain	-
Microorganisms in sewage treatment	PNEC STP: 16 mg/L
Soil	PNEC soil: 1.69mg/kg w
Air	no hazard identified

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8.2. Exposure controls

8.2.1 Appropriate engineering controls

8.2.1.1 Substance/mixture related measures to prevent exposure during identified uses: No specific measures

8.2.1.2 Structural measures to prevent exposure: No specific measures

8.2.1.3 Organisational measures to prevent exposure: No specific measures

8.2.1.4 Technical measures to prevent exposure:

- Provide local exhaust ventilation system or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value.
- Facilities for storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

8.2.2 Personal protection equipment

8.2.2.1 Eye and face protection:

- Tightly fitting safety goggles.
- Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

8.2.2.2 Skin protection

1) Hand protection : Handle with gloves. Gloves must be inspected prior to use. Wear suitable gloves tested to EN374

2) Other skin protection : Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product.

8.2.2.3 Respiratory protection :

- Use equipment for Respiratory protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
- Under conditions of frequent use or heavy exposure, respiratory protection may be needed.
- Respiratory protection (full facepiece)

8.2.2.4 Thermal hazards: No specific measures

8.2.3 Environmental exposure controls

8.2.3.1 Substance/mixture related measures to prevent exposure : Prevent entry into Waterways.

8.2.3.2 Instruction measures to prevent exposure: No specific measures

8.2.3.3 Organisational measures to prevent exposure: No specific measures

8.2.3.4 Technical measures to prevent exposure: No specific measures

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

A. Physical state : Solid

B. Color : Colourless

C. Odour : Not available

D. Melting point/Freezing point : 345 - 348 ℃

E. Initial boiling point and boiling range: Not available

F. Flammability : Non flammable

G. Upper/lower flammability or explosive limits : Not available

H. Flash point : Not applicable

I. Auto-ignition temperature : Not available

J. Decomposition temperature : Not available

K. pH : Not available

L. Kinematic viscosity(㎟/s) : Not available

M. Solubility(ies) : 120 mg/L (25 ℃)

N. Partition Coefficient(n-Octanol/Water) : Log Kow = 1.66 (25 ℃)

O. Vapor pressure : 0.0000032 Pa (25 ℃)

P. Density/Relative density : 1.53 g/㎤ (20 ℃)

Q. Relative Vapor density : Not available

R. Particle characteristics : Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes : Not available

9.2.2. Other safety characteristics : Not available

SECTION 10: Stability and reactivity

10.1. Reactivity :

- The product is stable.

10.2. Chemical stability :

- Incompatible with oxidizing agents.
- Stable under recommended storage and handling.

10.3. Possibility of hazardous reactions :

- Not considered as a product presenting risks of explosion.
- Some may burn but none ignite readily.

10.4. Conditions to avoid :

- Ignition sources as heat, spark, flame, etc.
- Contamination

10.5. Incompatible materials : Oxidizing

10.6. Hazardous decomposition products :

- Combustion may produce carbon oxides (CO, CO2).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

11.1.1 Acute toxicity

- Oral : LD50 > 5,000 mg/kg) (Rat, OECD Guideline 401) (Ref:Anon (1990), Reliability 2)
- Dermal : LD50 > 2,000 mg/kg (Rabbit, OECD Guideline 402) (Ref:Johnson W, Hatoum N & Boyne R (1990), Reliability 2)
- Inhalation(Vapour) : LC50 > 11,370 mg㎥ (Rat, OECD Guideling 403) (Ref:Kay J (1958), Reliability 2)

11.1.2 Skin corrosion/irritation : Not irritating, Primary dermal irritation index (PDII): 0 of max. 0 (mean) (Time point: 24, 48, 72 hours) (Rat, OECD Guideling 404) (Ref:Kay J (1958), Reliability 2)

11.1.3 Serious eye damage/irritation : Not irritating, Cornea score: 0 of max. 0 (mean) (Time point: 24-72h) (No reactions), Iris score: 0 of max. 0 (mean) (Time point: 24-72h) (No reactions), Conjunctivae score: 0.72 of max. 2 (mean) (Time point: 24-72h) (fully reversible within: 96h) (Erythema), Chemosis score: 0.67 of max. 2 (mean) (Time point: 24-72h) (fully reversible within: 96h) (Rabbit, OECD Guideline 405) (Ref:Reckers Andresen M, Hatoum N & Reed JM (1985), Reliability 2)

11.1.4 Respiratory or skin sensitization :

Respiratory sensitization : Not available

Skin sensitization: Not sensitising (Guinea pig, OECD Guideline 406) (Ref: Hatoum N & Johnson W (1991), Reliabililty 1)

11.1.5 Germ cell mutagenicity :

- *In vitro* - Negative (*S.typhimurium*, Bacterial reverse mutation assay, with and without metabolic activation, OECD Guideline 471) (Ref: Jones E & Churchill E (1991), Reliability 2)
  - Negative (*Mouse*, Mammalian cell gene mutation assay, met. act.: with and without; cytotoxicity: no, OECD Guideline 476) (Ref: Riach CG & Willington SE (1994), Reliability 1)

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• *In vivo* - Negative (*Mouse*, Micronucleus assay, OECD Guideline 474) (Ref: Gudi R & Krsmanovic L (2001), Reliability 1)

- Negative (*Rat*, Unscheduled DNA synthesis, OECD Guideline 486) (Ref:Fox V, Reliability 1)

11.1.6 Carcinogenicity : Not carcinogenicity (Ref:IARC, ACGIH, OSHA, NTP, EU CLP)

11.1.7 Reproductive toxicity : NOAEL (reproductive) (all): 20,000 ppm (nominal) (male/female) based on: test mat. (no effects seen on reproduction and development. Equivalent to 2,010.9 -2,324.3 mg/kg bw/d achieved pre-mating dose levels)) (Ref: Milburn, G.M. (2003a); Milburn, G.M. (2003b); Milburn, G.M. (2003c); Milburn, G.M. (2003d); Jacobsen, M. (2003), Reliability 1)

11.1.8 STOT-single exposure : Not available

11.1.9 STOT-repeated exposure : NOAEL: 1.6 % in diet (female) based on: test mat. (Bladder stones bodyweight effects and increased kidney weights at the highest concentration of 3%), LOAEL: 0.5 % in diet (male) based on: test mat. (Bladder and/or kidney stones were seen in all treated groups of males) (Rat) (Ref:Vogin E (1972), Reliability 2)

11.1.10 Aspiration hazard : Not available

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties : According to Regulation(EU) 2017/2100 and 2018/605, the substance not affects to endocrine system.

11.2.2 Other information: No other hazards have been identified

ECTION 12: Ecological information

12.1. Toxicity :

Acute (short-term) toxicity:

- Fish: LC50> 907 mg/L (*Leuciscus idus melanotus*, 96h, OECD Guideline 203) (Ref: Knacker, T., Zietz, E., Schallnass, H. and Diehl, T. (1993); Zietz, E. and Brodesser, J. (1993a), Reliability 1)
- Invertebrates: EC50> 952 mg/L (*Daphnia magna*, 48h, OECD Guideline 202) (Ref: Knacker, T., Zietz, E., Schallnass, H. and Reifenberg, P. (1993); Zietz, E. and Brodesser, J. (1993b), Reliability 1)
- Aquatic plants: EC50> 19 mg/L (*Pseudokirchnerella subcapitata*, 72 hr, OECD Guideline 201) (Ref:Anonymous, Reliability 1)

Chronic (long-term) toxicity:

- Fish: Not available

- Invertebrates: NOEC= 19.5 mg/L (*Daphnia magna*, 21d, OECD Guideline 211) (Ref:Anonymous, Reliability 1)
- Aquatic plants: NOEC= 1,000 mg/L (*Desmodesmus subspicatus*, 96 hr, OECD Guideline 201) (Ref:Knacker, T., Brodesser, J., Schallnass, H. and Reifenberg, P. (1993); Brodesser, J. and Heldt, C. (1993b), Reliability 1)

12.2. Persistence and degradability :

12.2.1. Abiotic Degradation:

- DT50= t1/2 (pH 7): > 96 h at 23 ℃ (OECD Guideline 201) (Ref: Knacker, T., Brodesser, J., Schallnass, H. and Reifenberg, P. (1993); Brodesser, J. and Heldt, C. (1993a), R, Reliability 1)

12.2.2. Physical- and photo-chemical elimination:

- Half-life (DT50): 8.18 d (Default setting, 25 ℃, 12-h day, 1.5E6 OH/㎤); 12.27 d (Northern hemisphere setting, 25 ℃, 24-h day, 0.5E6 OH/㎤) (Calculation) (Bealing, D.J. (2009), Reliability 2)

12.2.3. Biodegradation:

- 85% / 14d, Readily biodegradable (OECD Guideline 301 B) (Ref: Lebertz, H. (1991a), Reliability 1)

12.3. Bioaccumulative potential :

12.3.1. Partition coefficient n-octanol /water (log Kow):

- logKow= 1.66 (25 ℃) (Ref:QSAR)

12.3.2. Bioconcentration factor (BCF):

- BCF= 3.16 L/kg (Estimated) (Ref:Not available)

12.4. Mobility in soil :

12.4.1. Known or predicted distribution to environmental compartments: Not available

12.4.2. Surface tension: Not available

12.4.3. Adsorption/Desorption:

- Koc= 79.24 L/kg (Calculation) (Bealing, D.J., Reliability 2)

12.5. Results of PBT and vPvB assessment :

- This substance does not contain any substances that are assessed to be a PBT or a vPvB.

12.6. Endocrine disrupting properties

- According to Regulation(EU) 2017/2100 and 2018/605, the substance not affects to endocrine system.

12.7. Other adverse effects : Ozone layer hazard

- Not applicable

12.8. Additional information : Not available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

13.1.1 Product / Packaging disposal

- Empty containers should be taken to an approved waste handling site for recycling or disposal.

1) Waste codes / Waste designations according to LoW :

- Not classified as hazardous waste according to European Union regulations.

13.1.2 Waste treatment-relevant information

- Waste must be disposed of in accordance with directive 2008/98/EC.
- Waste must be disposed of in accordance with federal, state and local environmental control regulations

13.1.3 Sewage disposal-relevant information:

- Release to the environment or sewage system is prohibited.

13.1.4 Other disposal recommendations:

- Finish cleaning by spreading Water on the contaminated surface and dispose of according to local and regional authority requirements.

SECTION 14: Transport information

14.1. UN number : Not applicable

14.2. UN proper shipping name : Not applicable

14.3. Transport hazard class(es) : Not applicable

14.4. Packing group : Not applicable

14.5. Environmental hazards : Not applicable

14.6. Special precautions for user : Not applicable

14.7. Maritime transport in bulk according to IMO Instruments : Not available

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SECTION 15: Regulatory information

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

15.1.1 EU Regulation (EC) No. 1907/2006(REACH)/ Authorisations and/or restrictions on use :

- Authorisations(Annex XIV): Not applicable
- Restrictions on use(Annex XVII): Not applicable

15.1.2 Other EU regulations

- EU Seveso III Directive (2012/18/EU) - Qualifying Quantities of Dangerous Substances : Not applicable
- EU Persistent Organic Pollutants (850/2004) : Not applicable
- EU Paints, Varnishes, Vehicle Refinishing Products (2004/42/CE) – VOCs : Not applicable
- EU Industrial Emissions (2010/75/EU) - Integrated Pollution Prevention and Control Directive – List of Polluting Substances : Not applicable
- EU Fluorinated Gases (517/2014) - Global Warming Potential : Not applicable
- EU Substances Depleting the Ozone layer (1005/2009) : Not applicable
- EU Export and Import Restrictions (649/2012) - Chemicals and Articles Subject to Export Ban : Not applicable
- Germany VwVwS Annex reference : WGK 1

15.2. Chemical safety assessment

- No Chemical Safety Assessment has been carried out for this substance by the Supplier.

SECTION 16: Other information

16.1. Indication of changes / Date of issue

- Date of issue : 26-12-2022
- Indication of changes : Rev. 0, -

16.2. Abbreviations and acronyms

- ECHA : European Chemicals Agency
- EU CLP : EU Regulation 1272/2008 on the classification, labelling and packaging of chemicals and mixtures)
- GLP : Good Laboratory Practice
- NFPA : National Fire Protection Association
- EL50 : 50% Effect Loading dose
- LC50 : Lethal Concentration 50% kill
- LD50: Lethal Dose 50% kill

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- LL50 : Lethal loading rate 50% kill
- TWA : Time weight Average
- KOSHA : The Korea Occupational Safety and Health Agency

16.3. Key literature references and sources for data

- ACGIH
- CAMEO Chemicals NOAA
- ChemIDplus
- ECHA
- ECOSAR
- Emergency response guide book
- EPI Suite
- HSDB
- HPVIS
- IARC
- ICSC
- INCHEM
- IPCS
- NITE
- OECD SIDS
- PubChem
- Recommendations on the transport of dangerous goods

16.4. Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP] : Not classified

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ANNEX Ⅰ. Exposure scenarios (Chemical Safety Assessment)

1. Workers exposure

The need to carry out a human health exposure assessment and risk characterisation for isophthalic acid was assessed under the terms of the ECHA document "Guidance on information requirements and chemical safety assessment" Part B, draft chapter B.8 which deals with the scope of the exposure assessment.

According to this guidance chapter, it is not required to carry out an exposure assessment and risk characterisation for human health if it can be demonstrated that there is "no hazard" for the human populations. In order to assess the need or not to conduct an exposure assessment it is important to review the human health related endpoint and to establish as to whether or not there is a potential risk to humans when using the substance. The guidance sets out some criteria in a flow chart as follows:

1 - It was established that isophthalic acid is not a PBT (or vPvB) substance. Therefore, it can be concluded that exposure assessment and risk characterisation should not be required.

2 - The substance is not classified for acute and long term toxicity (systemic and local effects) according to Directive 67/548/EEC and Regulations (EC) 1272/2008). Therefore, it can be concluded that exposure assessment and risk characterisation should not be required.

3 – There are no additional systemic effects that would trigger a potential risk to be controlled. In a repeated dose oral toxicity study, no deaths occurred and there were no signs of toxicity. Bodyweights were markedly reduced at the highest dose level of 3% (initially 5%). No effects were seen on haematological and clinical chemistry parameters; urinalysis revealed the presence of red blood cells and crystals in the urine of treated animals. Findings were associated with increased kidney weights but did not have any gross or microscopic pathological correlates. The available studies do not indicate any marked toxicity or effects at relevant dose levels. It is unlikely that the human population would be at risk when using isophthalic acid.

Based on the above, it can be concluded that isophthalic acid does not pose a risk to the human populations and meets the criteria for classification of "no hazard" according to REACH. No further investigation is therefore required.

2. Consumer exposure

As discussed above isophthalic acid is considered to be non-hazardous to human health based on the REACH characterisation criteria. As such no exposure estimation for the consumer exposure is required.

2.1. Indirect exposure of humans via the environment (oral)

Indirect exposure of humans via the environment is unlikely due to lifecycle of substance, its physico-chemical properties, ready biodegradation and hydrolysis in water. Therefore, the risk of secondary/indirect exposure is expected to be negligible. Isophthalic acid is readily biodegradable. Isophthalic acid may therefore be expected to degrade rapidly, and to be completely mineralised, i.e. converted to CO2 and H2O without forming any recalcitrant metabolites. Isophthalic acid and its degradation intermediates are non-persistent, therefore indirect exposure of humans could not occur. Removal in the STP is expected to be highly efficient and so secondary exposure of the other receiving compartments is expected to be minimal. Similarly contamination of food crops or animals used as human food sources is not envisaged.

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2.2. Environmental exposure

The need to carry out an environmental exposure assessment and risk characterisation for isophthalic acid has been assessed under the terms of the ECHA document "Guidance on information requirements and chemical safety assessment" Part B, draft chapter B.8 which deals with the scope of the exposure assessment.

This guidance chapter sets out the criteria for which a classification of "no hazard" may be derived for the purposes of REACH and relates the classification to the need to carry out the exposure assessment. It is considered that isophthalic acid meets all the criteria thus allowing a classification of "no hazard" for the environment to be derived and, as such, it is determined that no risk characterisation for the environment is required. Details of the relevant properties of isophthalic acid which determine the lack of any hazard are listed below. The risk of exposure of man via inhalation is dealt with separately in the human/worker exposure assessment sections.

In order to derive a classification of "no hazard" for the environment the following criteria (which are well below the classification of dangerous in accordance with Directive 67/548/EEC and Regulations (EC) 1272/2008) should be met:

1. The substance should be readily biodegradable. As demonstrated in section 4.1.2.1.2 isophthalic acid may be considered readily biodegradable based on the results of two studies. In these studies, performed in accordance with OECD ready biodegradability guidelines, the mineralisation of isophthalic acid comfortably exceeded the relevant pass criteria. As such, it is considered that this classification criterion is met.
2. The substance should have a very low potential for bioaccumulation with a log Kow less than 2 and/or a BCF of less than 10. In public literature, isophthalic acid has a known BCF value of 1.66 (Hansch, C. et al., 1995). The potential for isophthalic acid to bioaccumulate in the tissues of organisms that inhabit aquatic or terrestrial matrices contaminated with IPA is therefore negligible. The risk that isophthalic acid may biomagnify through successive trophic levels of aquatic or terrestrial food chains is consequently also negligible.
3. The aquatic toxicity should fulfil both of the following conditions:
   a. Acute EC50 or LC50 values should be > water solubility. IPA is moderately soluble in water (100-1000 mg/L). The water solubility of IPA is 120 mg/L at 25℃. The LC50 in fish, algae and Daphnia is greater than the water solubility therefore this criterion is met.

   Acute toxicity studies in Daphnia derived EC50 values of up to 952 mg/L which indicates no potential for toxicity.

   Three reliable, GLP-compliant short-term studies are available in which IPA was treated with NaOH solution to convert the free acid to its highly soluble sodium isophthalate salt(s) prior to exposure to fish, Daphnia and algae. No adverse effects occurred in these studies, up to and including the highest nominal IPA-equivalent concentrations of 1000 mg/L. The lowest endpoint from these three studies (the 96 h LC50 for L. idus melanotus) was > 907 mg IPA-equiv/L (mean measured). These studies demonstrate the low intrinsic toxicity of isophthalate to aquatic biota, and - taking into account its susceptibility to rapid biodegradation - provide assurance that isophthalic acid does not present a long-term and/or delayed danger to the structure and/or functioning of aquatic ecosystems.

   b. Chronic/long-term NOECs should be greater than 10 mg/L. Read-across to terephthalic acid is considered to be acceptable. A study of the chronic toxicity of

terephthalic acid on the reproduction of Daphnia magna provided a NOEC value of 19.5 mg/L. The 96-hour NOEC values for effects on the growth rate of two species of freshwater algae are 1000 and 996 mg/L respectively. In all cases the NOEC was the highest concentration tested.

It is considered that isophthalic acid comfortably meets the above criteria for the aquatic compartment and no toxicity risk for aquatic organism is indicated.
In addition to these criteria no risk to the terrestrial environment is indicated for Isophthalic acid based on the studies presented in section 7.2 and there is no evidence for endocrine activity. As IPA is readily biodegradable the effect of the substance on soil macroorganisms is negligible.
Given the above parameters it can be concluded that isophthalic acid poses no risk to the environment and as such as classification of "no hazard" may be derived based in the REACH criteria. In addition to this it can be concluded based on the relevant guidance document that there is no need to assess the oral exposure of man via the environment. As such no exposure assessment or risk characterisation is presented or required for risk to the environment or risk to man via the environment.

RISK CHARACTERISATION

1. Human health

1.1. Workers

As discussed, isophthalic acid does not pose any hazard to the worker based on the strict REACH classification criteria. As such no worker exposure assessment or risk characterisation is required. As such the RCRs are not derived as no risk to the worker is indicated for isophthalic acid.

1.2. Consumer

As discussed, isophthalic acid does not pose any hazard to the consumer based on the strict REACH classification criteria. As such no consumer exposure assessment or risk characterisation is required. As such the RCRs are not derived as no risk to the consumer is indicated for isophthalic acid.

1.2.1. Indirect exposure of humans via the environment

As discussed, isophthalic acid does not pose any hazard humans via the environment based on the strict REACH classification criteria. As such no exposure assessment or risk characterisation is required for humans via the environment.

1.2.2. Environment

As discussed, isophthalic acid does not pose any hazard to the environment based on the strict REACH classification criteria. As such no environmental exposure assessment or risk characterisation is required. As such environmental RCRs are not derived as no risk to the environment is indicated for isophthalic acid.