

ECHA's Dissemination website

Infocard & Brief Profiles Overview

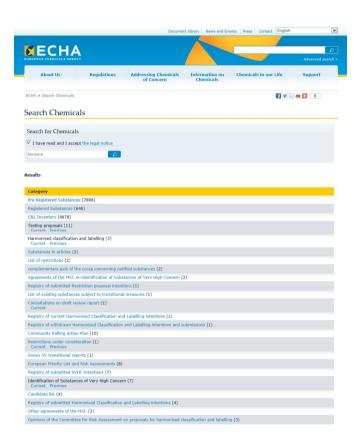
03 December 2013

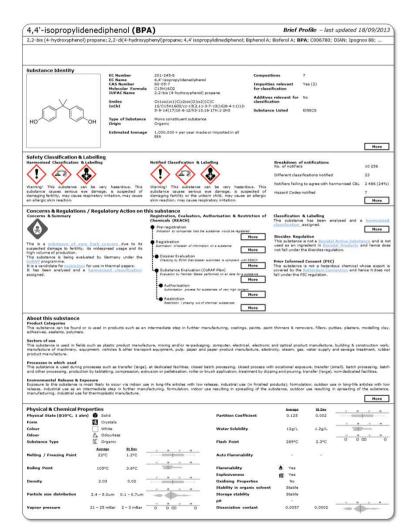
Eoin BRENNAN





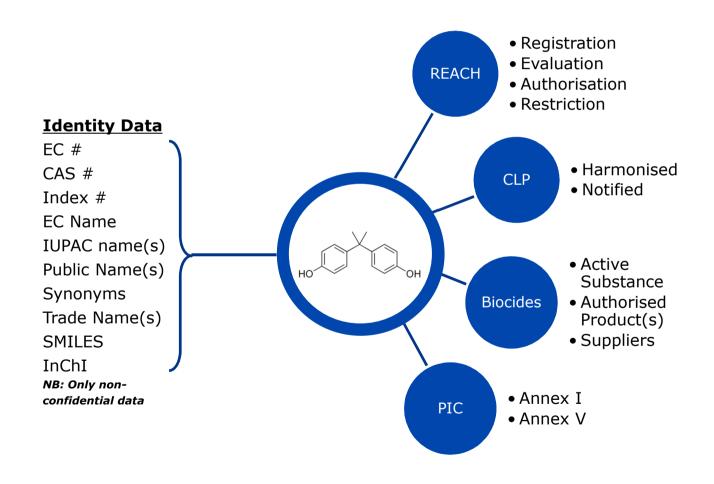
The Future...







Substance centric model



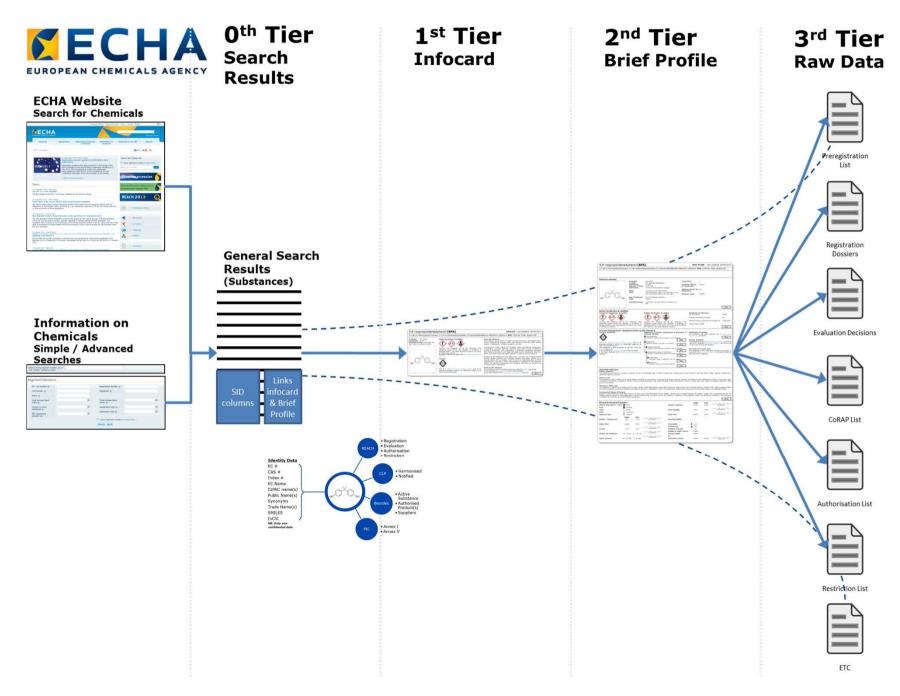


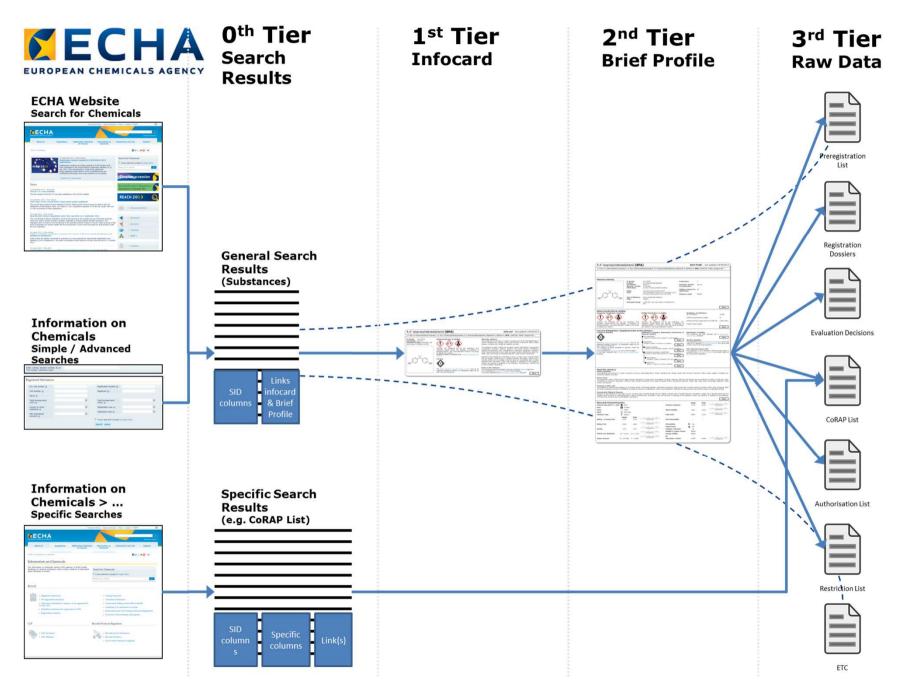
Tiered approach

- 0th tier with search result
- 1st tier focusing on highest level summarised information Infocard

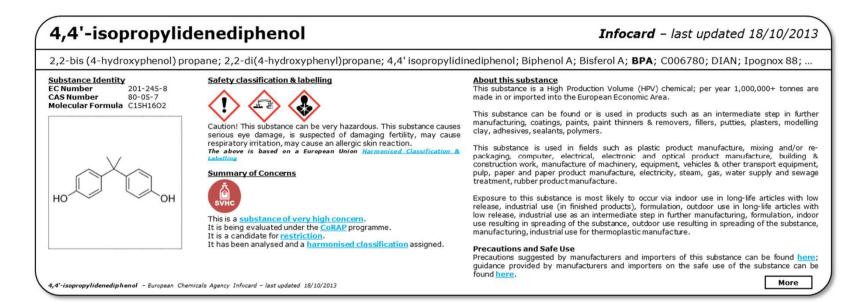
3 main objectives:

- · Allow users to identify the substance
- Provide high-level information to concerned citizens
- Provide an overview of key regulatory processes related to the substances
- 2nd tier with extended information Brief Profile
 - The objective of the second layer is to provide summary data on all key aspects of a substance
- 3rd tier with raw data



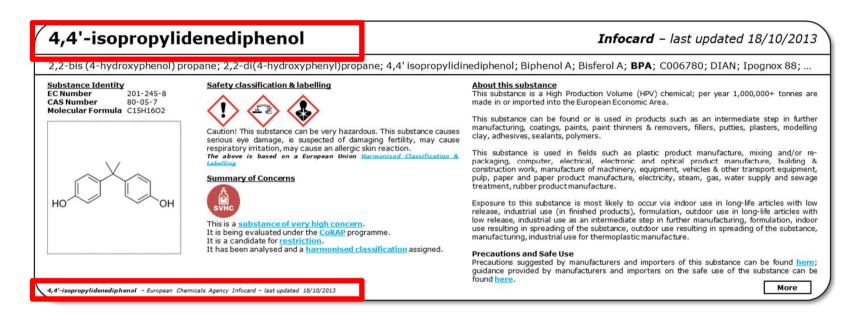






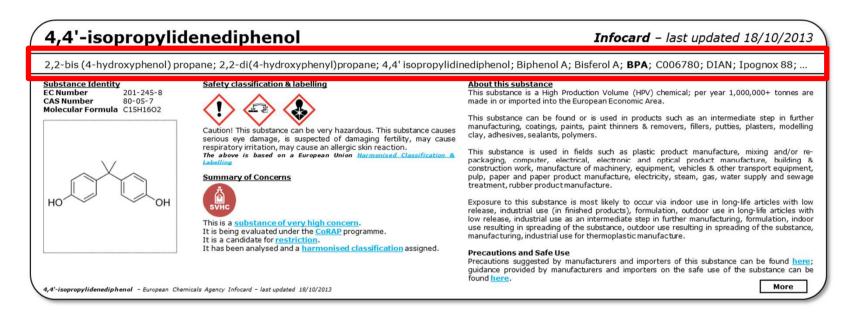
- Simple high level overview of a substance
- Understandable to the broadest possible audience
- Most widely relevant data summarised





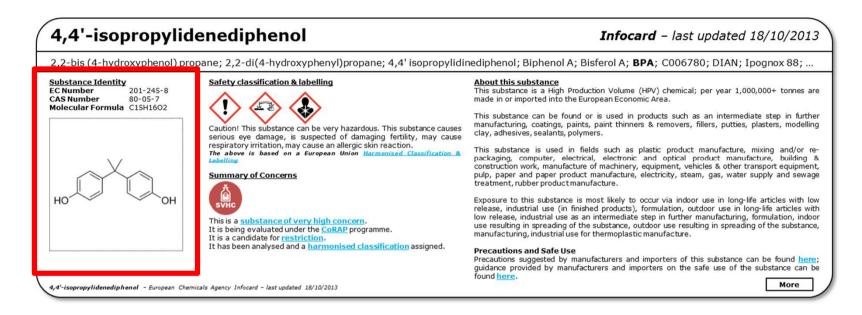
Substance ID – ECHA master name





 Substance ID – synonyms, non-confidential trade names, other names

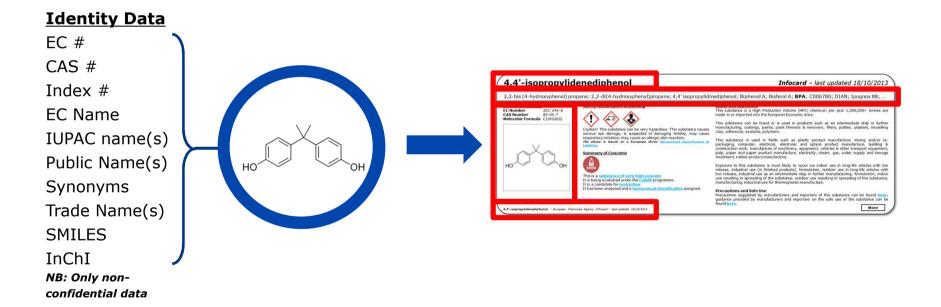




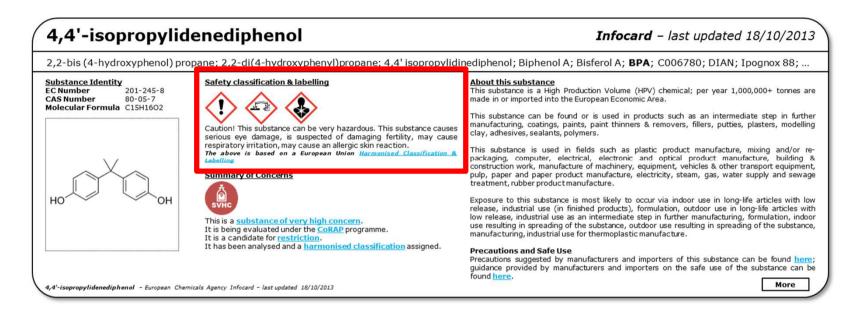
 Substance ID – numerical identifiers, molecular formula, molecular image



Substance Master List



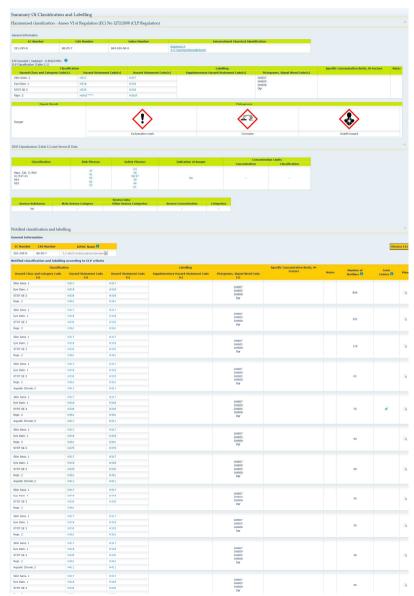




- Safety classification and labelling
- Automatically generated
 - From Harmonised C&L if available
 - Otherwise based on <u>all submitted</u> C&L notifications

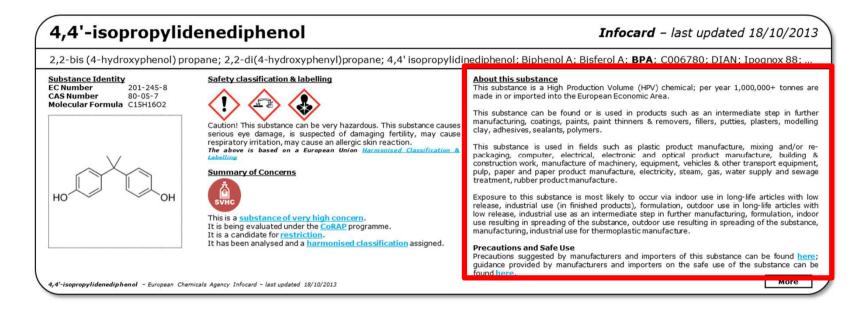


C&L – given simply and understandably









- "About this Substance"
- Automatically generated
 - From all non-confidential tonnages (as currently disseminated)
 - From all non-confidential uses in all REACH registrations for the substance

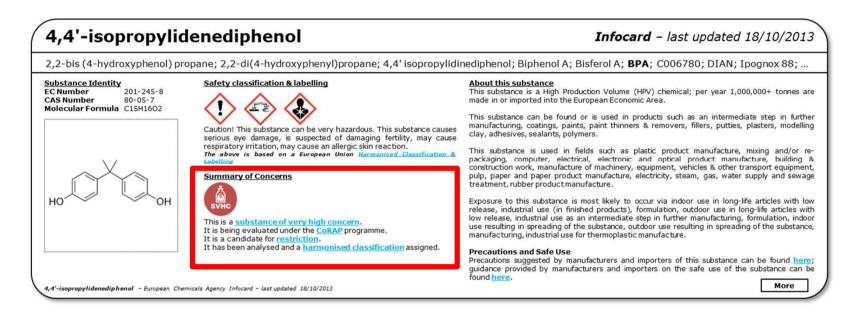


Uses – given simply and understandably

dentified uses	
nformation on uses	
anufacture	
	Industrial Manufacturing of Bisphenol A
Process category	PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
Environmental release category	ERC 1: Manufacture of substances
	Industrial Use of Bisphenol A as Laboratory Reagent
Process category	PROC 15: Use as laboratory reagent
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- Summary of Concerns
- Highlights critical characteristics of the substance
 - "Red traffic lights" considered are SVHC, CMR, PBT
- Indicates key regulatory action(s) for the substance



Summary of concerns

- Key regulatory processes
- Master list identifies in which the substance is concerned
- Simple text for each process
- Key traffic light indicators if relevant conditions are met





Brief Profile

4,4'-isopropylidenediphenol

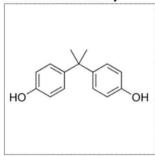
Brief Profile - last updated 18/10/2013

2,2-bis (4-hydroxyphenol) propane; 2,2-di(4-hydroxyphenyl)propane; 4,4' isopropylidinediphenol; Biphenol A; Bisferol A; BPA; C006780; DIAN; Ipognox 88; ...

Introduction

The following is a brief profile summarising the non-confidential data on this substance held in the databases of the European Chemicals Agency (ECHA). Please note that this brief profile is generated automatically based on the data available at the time of generation. The data remains the responsibility of its respective owners and ECHA does not assure the quality and correctness of the information. This brief profile is covered by the ECHA Legal Disclaimer.

Substance Identity



EC Number EC Name CAS Number Molecular Formula **IUPAC Name**

Smiles InChI

Type of Substance

Oc1ccc(cc1)C(c2ccq(O)cc2)(C)C 1S/C15H16O2/c1-15(2,11-3-7-13(16)8-4-11)12-5-9-14(17)10-6-12/h3-10,16-17H,1-2H3

2,2-bis (4-hydroxyphenol) propane

Mono constituent substance Organic

4,4'-isopropylidenediphenol

201-245-8

80-05-7

C15H16O2

Compositions

Impurities relevant for Yes (2) classification

Additives relevant for No classification

Substance Listed EINECS

More

Safety Classification & Labelling

Harmonised Classification & Labelling (ATP 4 - Sep 2013)







Caution! This substance can be very hazardous. This substance causes serious eye damage, is suspected of damaging fertility, may cause respiratory irritation, may cause an allergic skin

More

Notified Classifications & Labellings

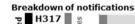


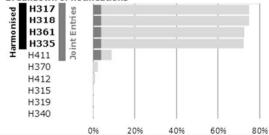




Caution! This substance can be very hazardous. This substance causes serious eye damage, is suspected of damaging fertility, may cause respiratory irritation, may cause an allergic skin

The above is compiled based on all of the classifications and labellings notified to ECHA by industry





Concerns & Regulations / Regulatory Action on this substance **Summary of Concerns**

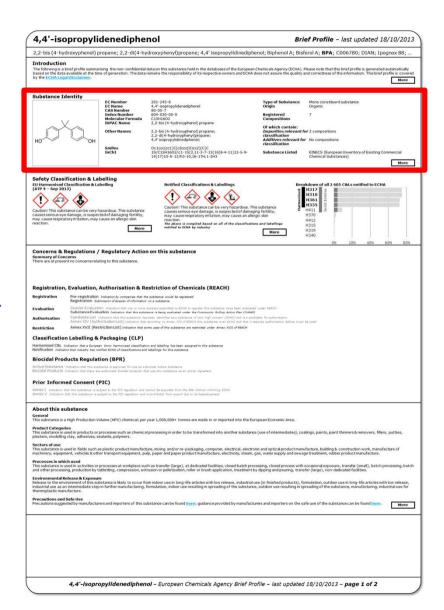
This is a <u>substance of very high concern</u>. It is being evaluated under the <u>CoRAP</u> programme. It is a candidate for <u>restriction</u>. It has been analysed and a <u>harmonised classification</u> assigned.





Substance ID

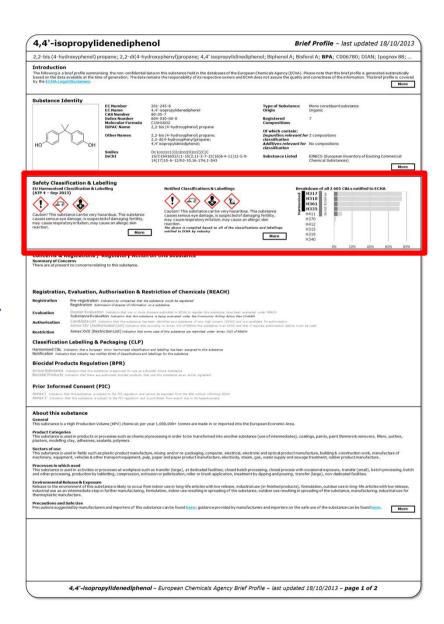
- Substance master list
- More nonconfidential identifiers
- Data on compositions submitted, impurities & additives relevant to classification





C&L - expanded

- C&L Inventory data
- Harmonised entry displayed if it exists
 - And ATP date
- All notifications compiled & shown
- Breakdown of notifications
 - Agreement with harmonised
 - Agreement with joint entry



Concerns & Regulations / Regulatory Action on this substance

Summary of Concerns

There are at present no concerns relating to this substance.

Registration, Evaluation, Authorisation & Restriction of Chemicals (REACH)

Registration Pre-registration Indication by companies that the substance would be registered

Registration Submission of dossier of information on a substance

Evaluation Dossier Evaluation Indication that one or more dossiers submitted to ECHA to register this substance have been evaluated under REACH

Substance Evaluation Indication that this substance is being evaluated under the Community Rolling Action Plan (CoRAP)

Authorisation Candidate List Indication that this substance has been identified as a substance of very high concern (SVHC) and is a candidate for authorisation

Annex XIV (Authorisation List) Indication that according to Annex XIV of REACH this substance is an SVHC and that it requires authorisation before it can be used

Restriction Annex XVII (Restriction List) Indication that some uses of this substance are restricted under Annex XVII of REACH

Classification Labelling & Packaging (CLP)

Harmonised C&L Indication that a European Union harmonised classification and labelling has been assigned to this substance Notification Indication that industry has notified ECHA of classifications and labellings for this substance

Biocidal Products Regulation (BPR)

Active Substance Indication that this substance is approved for use as a Biocidal Active Substance
Biocidal Products Indication that there are authorised biocidal products that use this substance as an active ingredient

Prior Informed Consent (PIC)

Annex I Indication that this substance is subject to the PIC regulation and cannot be exported from the EEA without informing ECHA Annex V Indication that this substance is subject to the PIC regulation and is prohibited from export due to its hazardousness

About this substance

General

This substance is a High Production Volume (HPV) chemical; per year 1,000,000+ tonnes are made in or imported into the European Economic Area.

Product Categories

This substance is used in products or processes such as chemical processing in order to be transformed into another substance (use of intermediates), coatings, paints, paint thinners & removers, fillers, putties, plasters, modelling clay, adhesives, sealants, polymers.

Sectors of use

This substance is used in fields such as plastic product manufacture, mixing and/or re-packaging, computer, electrical, electronic and optical product manufacture, building & construction work, manufacture of machinery, equipment, vehicles & other transport equipment, pulp, paper and paper product manufacture, electricity, steam, gas, water supply and sewage treatment, rubber product manufacture.

Processes in which used

This substance is used in activities or processes at workplace such as transfer (large), at dedicated facilities, closed batch processing, closed process with occasional exposure, transfer (small), batch processing, batch and other processing, production by tabletting, compression, extrusion or pelletisation, roller or brush application, treatment by dipping and pouring, transfer (large), non-dedicated facilities.

Environmental Release & Exposure

Release to the environment of this substance is likely to occur from indoor use in long-life articles with low release, industrial use (in finished products), formulation, outdoor use in long-life articles with low release, industrial use as an intermediate step in further manufacturing, formulation, indoor use resulting in spreading of the substance, outdoor use resulting in spreading of the substance, manufacturing, industrial use for thermoplastic manufacture.

Precautions and Safe Use

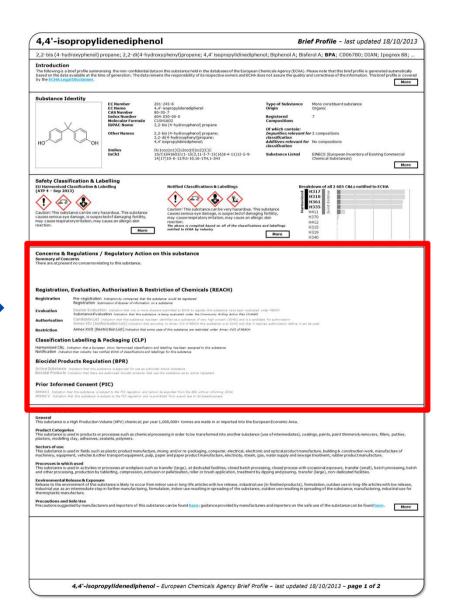
Precautions suggested by manufacturers and importers of this substance can be found here; guidance provided by manufacturers and importers on the safe use of the substance can be found here.

More



Regulatory Action

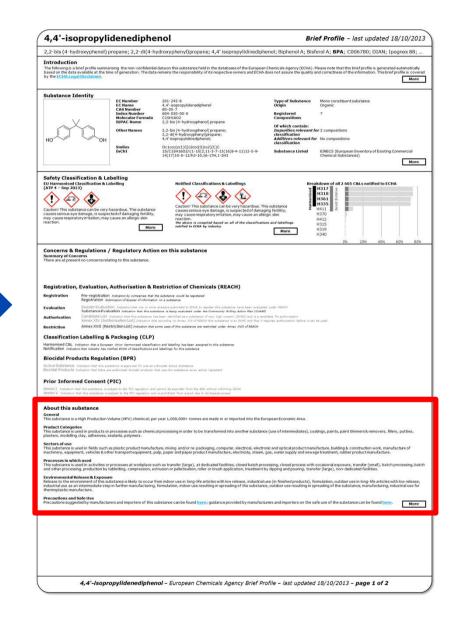
- From substance master list
- Key concerns indicated
- Breakdown by
 - Regulation (REACH, CLP, BPR, PIC)
 - Regulatory processes within regulations
- Indicates status of substance in all processes at a glance





About – expanded

- Headings to clarify topic of each paragraph – based on use descriptor types
 - Product category (PC)
 - Sector of use (SU)
 - Processes in which used (PROC)
 - Environmental release categories (ERC)
- Add processes in which used



2,2-bis (4-hydroxyphenol) propane; 2,2-di(4-hydroxyphenyl) propane; 4,4' isopropylidinediphenol; Biphenol A; Bisferol A; BPA; C006780; DIAN; Ipognox 88; ... **Physical & Chemical Properties** Flammability **Appearance** Physical state (20°C, 1 atm) Solid **Explosive properties** Form Crystals Self-ignition temperature Colour White Vapour pressure 0.00161 - 1.297 x 10⁻⁷ hPa (@ 20 - 50 °C) Odour Odourless 0.09 - 10.13 hPa (@ 170 - 190°C) Substance type Organic Molecular weight 228.29 Water solubility 120 - 340 mg/L (@ 25 - 83°C and pH 4 - 10) Density 1.06 - 1.2 g/cm3 (@ 20 - 160°C) Flash point 207 - 227 °C (@ ~1 atm) Viscosity No (usable) data submitted / available Octanol-water partition 2.20 - 3.32 logKow (@ ~21.5°C and pH 3 - 6.7) Melting / freezing point 150 - 157°C (@ 1 atm) cooefficient (LogKow) **Boiling point** 220°C @ 5.22 hPa 250 - 252°C (@ 17 hPa) Dissociation constant 9.73 - 10.48220 - 360°C (@ 1 atm) More Stability in organic solvents No (usable) data submitted / available **Environmental fate and pathways BIOACCUMULATION** STABILITY 20 - 67 BCF (whole body weight @ 15 µg/l) Aquatic / sediment Phototransformation in air 0.13 days (calculated) **Terrestrial** No (usable) data submitted / available Phototransformation in water 17.4 - 32.2 hours (river / lake fulvic acids) Phototransformation in soil Not justified TRANSPORT & DISTRIBUTION Hydrolysis No (usable) data submitted / available Adsorption 890 L/kg Koc Desorption 1090 L/kg Koc **BIODEGRADATION** Henry's Law constant 0.000312 other: mPa m³/mol (@ 25°C and 1013 hPa) In water: screening tests 74.7 - 81.4% (over 28 days) Distribution modelling: In water & sediment: 0.5 - 2.6 days Air 0.01% simulation tests Water 32.9% In soil 0.5 - 2.6 days Soil 65.3% Mode of degradation (actual No (usable) data submitted / available More Sediment 1.8% **Ecotoxicological information** Predicted No-Effect Concentration (PNEC) values The PNEC value is the concentration of the substance below which adverse effects in the environment Sediments (freshwater) 2.2 mg/kg sediment dw are not expected to occur. Sediments (marine water) 0.44 mg/kg sediment dw Freshwater 0.018 mg/L Sewage treatment plant 320 mg/L 0.016 mg/L Soil 3.7 mg/kg soil dw **Marine water** Intermittent releases to water 0.01 mg/L Air - (no hazard identified) Secondary poisoning 13.8 mg/kg food No (usable) data submitted / available More STP **Toxicological information** Derived No-Effect Level (DNEL) - for WORKERS Derived No-Effect Level (DNEL) - for the GENERAL POPULATION The DNEL is the level of exposure above which a human should not be exposed to a substance. INHALATION INHALATION Systemic effects Systemic effects Long term 10 mg/m³ - most sensitive: repeated dose toxicity Long term 0.25 mg/m³ - most sensitive: repeated dose toxicity 10 mg/m³ - most consitive, repeated dose toxicity E ma/m³ - most consitive; repeated dose toxicity Acuto Acuto

Toxicological information

Derived No-Effect Level (DNEL) - for WORKERS

The DNEL is the level of exposure above which a human should not be exposed to a substance.

INHALATION

- Systemic effects
- Long term 10 mg/m³ most sensitive: repeated dose toxicity
 Acute 10 mg/m³ most sensitive: repeated dose toxicity
- Local effects
- Long term
 10 mg/m³ most sensitive: irritation (respiratory tract)
 Acute
 10 mg/m³ most sensitive: irritation (respiratory tract)

DERMAL

- Systemic effects
- Long term
 1.4 mg/kg bw/day most sensitive: repeated dose toxicity
 Acute
 1.4 mg/kg bw/day most sensitive: repeated dose toxicity
- Local effects
- Long termNo dataAcuteNo data

EYES



Derived No-Effect Level (DNEL) - for the GENERAL POPULATION

INHALATION

- Systemic effects
 - Long term 0.25 mg/m³ most sensitive: repeated dose toxicity
 Acute 5 mg/m³ most sensitive: repeated dose toxicity
- Local effects
- Long term
 5 mg/m³ most sensitive: irritation (respiratory tract)
 Acute
 5 mg/m³ most sensitive: irritation (respiratory tract)

DERMAL

- Systemic effects
 - o Long term 0.7 mg/kg bw/day most sensitive: repeated dose toxicity
 o Acute 0.7 mg/kg bw/day most sensitive: repeated dose toxicity
- Local effects
 - Long term No data
 Acute No data

EYES

No data

ORAL

- Systemic effects
- Long term 0.05 mg/kg bw/day most sensitive: repeated dose toxicity
 Acute 0.05 mg/kg bw/day most sensitive: repeated dose toxicity

More

Disclaimer

This brief profile was based on all of the non-confidential data contained in ECHA's databases at the time it was generated. Please be aware that as additional data is submitted to ECHA the brief profile will also be updated to reflect the new situation. All data remains the property of its respective owners. Use this brief profile at your own risk. Note that the brief profile is a summary and so not all data will be displayed. For a comprehensive overview of the substance properties it is recommended to complete set of data. This information has not been reviewed or verified by the Agency or any other authority. The Agency cannot guarantee the correctness of the information in these databases and the various Regulations do not permit ECHA to make modifications to the data submitted. The content is subject to change without prior notice. Reproduction or further distribution of this information may be subject to copyright protection. Use of the information without obtaining the permission from the owner(s) of the respective information might violate the rights of the owner. The Agency does not take any responsibility whatsoever for any copyright or other infringements that may be caused by using the information.

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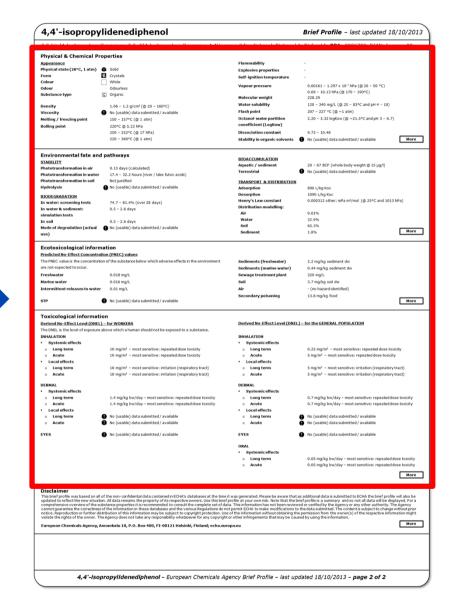
More

4,4'-isopropylidenediphenol - European Chemicals Agency Brief Profile - last updated 18/10/2013 - page 2 of 2



Scientific data

- Issue:
 - Many ways to indicate endpoint results
 - Many measurement conditions
 - Mostly insufficient data for statistical treatment
- Proposed solution:
 - Summarise max-min of result at max(es)min(s) of condition(s)





Conclusion

- Complex data on substances can be summarised
- Algorithms & logic exist already as prototype versions
- With foundation in place there are many possibilities for enhancements
 - Key concerns additional data
 - More coverage of regulatory processes
 - Precautions & safe uses submitted to ECHA (P-codes)
 - Highlight further range of C&L notifications & promote agreement
 - Highlight where data is not provided to ECHA (in a usable way)
 - Possibility to allow users to indicate incorrect data and request corrections