

Annex XV dossier

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CATEGORY 1A OR 1B CMR, PBT, vPvB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance name: 1,2-Benzenedicarboxylic acid, di-C₇₋₁₁-branched and linear alkyl esters
(DHNUP)

EC number: 271-084-6

CAS number: 68515-42-4

Submitted by: Danish Environmental Protection Agency - Denmark

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EC number: 271-084-6

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- The substance is proposed to be identified as a substance meeting the criteria of Article 57(c) of Regulation (EC) No 1907/2006 (REACH) owing to its classification as toxic for reproduction 1B¹, which corresponds to classifications as toxic for reproduction category 2².

Summary of how the substance meets the CMR (1A or 1B) criteria

DHNUP (1,2-Benzenedicarboxylic acid, di-C₇₋₁₁ -branched and linear alkyl esters) is listed by Index number 607-480-00-6 in Regulation (EC) No 1272/2008 and classified in Annex VI, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as toxic for reproduction, Repr. 1B (H360Df: “May damage the unborn child. Suspected of damaging fertility). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is toxic for reproduction category 2 (R61: “May cause harm to the unborn child”).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

Registration number(s) of the substance or of substances containing a given constituent/impurity or leading to the same transformation or degradation products:

Not available.

¹ Classification in accordance with Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances.

² Classification in accordance with Regulation (EC) No 1272/2008, Annex VI, part 3, Table 3.2 List of harmonised classification and labelling of hazardous substances (from Annex I to Council Directive 67/548/EEC).

PART I

JUSTIFICATION

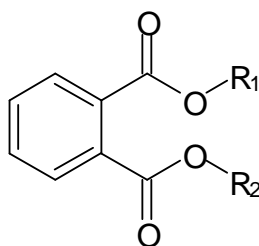
1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	271-084-6
EC name:	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters
CAS number (in the EC inventory):	68515-42-4
CAS number:	68515-42-4
CAS name:	1,2-Benzenedicarboxylic acid, di-C ₇₋₁₁ -branched and linear alkyl esters
IUPAC name:	Di-C7-11-(linear and branched)-alkyl phthalate
Index number in Annex VI of the CLP Regulation	607-480-00-6
Molecular formula:	C ₂₂ H ₃₄ O ₄ –C ₃₀ H ₅₀ O ₄
Molecular weight range:	362 – 474
Synonyms:	Dialkyl phthalate (C ₇₋₁₁) branched and linear phthalate ester; 711P; D711P; Di-711-phthalate; Dialkyl(C ₇₋₁₁ -branched and linear) phthalate; Di(heptyl, nonyl, undecyl) phthalate (DHNUP); Di(heptyl, nonyl, undecyl) phthalate (mixed isomers); Phthalic acid, dialkyl (C7-C11) ester; Santicizer 711 ³

³ [Environment Canada 2009]

Structural formula:

R_1 and R_2 can be linear or branched

1.2 Composition of the substance

This substance is a UVCB (Unknown or Variable Composition, Complex Reaction Products, or Biological Materials), and may thus be characterized by a variety of structures. The formula given in section 1.1 represents a representative chemical formula and a general chemical formula (minimum to maximum number of atoms)

1.3 Physico-chemical properties**Table 2: Overview of physicochemical properties**

Property	Value	Remarks
Physical state at 20°C and 101.3 kPa	<i>Liquid</i>	<i>IUCLID dataset- [ECB 2000b]*</i>
Melting/freezing point	<i>-57 °C (pour point)</i>	<i>IUCLID dataset- [ECB 2000b]*</i>
Boiling point	<i>235-278 °C at 7 hPa</i>	<i>IUCLID dataset- [ECB 2000b]*</i>
Vapour pressure	<i><10 Pa at 20 °C</i>	<i>IUCLID dataset- [ECB 2000b]*</i>
Water solubility	<i>0.1 mg/L at 20 °C pH neutral</i>	<i>IUCLID dataset- [ECB 2000b]*</i>
Partition coefficient n-octanol/water (log value)	<i>ca. 4.8</i>	<i>IUCLID dataset- [ECB 2000b]*</i>
Dissociation constant	<i>No data</i>	<i>IUCLID dataset- [ECB 2000b]*</i>
Density	<i>969-973 kg/m³ at 20 °C</i>	<i>IUCLID dataset- [ECB 2000b]*</i>

* According to [Environment Canada 2009] the physico-chemical properties are based on a test chemical named Palatinol[®] 711P, a trade name representing the following six CAS Numbers: 85507-79-5, 68515-44-6, 68515-45-7, 111381-89-6, 111381-90-9 and 111381-91-0. It is notable that one of the components of DHNUP, diundecyl phthalate, (CAS No. 3648-20-2), is replaced by diundecyl phthalate, branched and linear (CAS No. 85507-79-5), in Palatinol[®] 711P. The IUCLID dataset, however, does not mention Palatinol[®] 711P in this context, and gives the impression that test results is based on experiments with DHNUP (CAS No 68515-42-4). [Environment Canada 2009] has in their assessment considered Palatinol[®] 711P to be equivalent to DHNUP

2 HARMONISED CLASSIFICATION AND LABELLING

DHNUP (1,2-Benzenedicarboxylic acid, di-C₇₋₁₁-branched and linear alkyl esters) is listed by Index number 607-480-00-6 in Regulation (EC) No 1272/2008 as follows:

Table 3: Classification according to part 3 of Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No	International Chemical Identification	Classification *1		Labelling			Specific Conc. Limits, M-factors	Notes
		Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
607-480-00-6	1,2-Benzenedicarboxylic acid, di-C ₇₋₁₁ -branched and linear alkyl esters	Repr. 1B	H360Df	GHS08 Dgr	H360Df	H360Df		

Hazards statement code: H360Df: May damage the unborn child. Suspected of damaging fertility.

Table 4: Classification according to part 3 of Annex VI, Table 3.2 (list of harmonized classification and labelling of hazardous substances from Annex I of Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008

Index No	International Chemical Identification	Classification	Labelling	Concentration Limits	Notes
607-480-00-6	1,2-Benzenedicarboxylic acid, di-C ₇₋₁₁ -branched and linear alkyl esters	Repr. Cat. 2; R61 Repr. Cat. 3; R62	T R: 61-62 S: 53-45		

3 ENVIRONMENTAL FATE PROPERTIES

Not relevant for this type of dossier.

4 HUMAN HEALTH HAZARD ASSESSMENT

See section 2 on Harmonised Classification and Labelling.

5 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant for this type of dossier.

6 CONCLUSIONS ON THE SVHC PROPERTIES

6.1 CMR assessment

DHNUP (1,2-Benzenedicarboxylic acid, di-C7-11 -branched and linear alkyl esters) is listed by Index number 607-480-00-6 in Regulation (EC) No 1272/2008 and classified in Annex VI, Part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as toxic for reproduction, Repr. 1B (H360Df: “May damage the unborn child. Suspected of damaging fertility). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is toxic for reproduction category 2 (R61: “May cause harm to the unborn child”).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

PART II

1 INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

1.1 INFORMATION ON MANUFACTURE, IMPORT/EXPORT AND USES – CONCLUSIONS ON EXPOSURE

Based on information from European manufacturers of phthalates and The European Council for Plasticisers and Intermediates (ECPI), the substance seems not (anymore) to be manufactured in the EU or imported to the EU.

One EU based producer of electrical cables reported the use of DHNUP in their production of certain cable types in amounts of 100-700 tonnes/year. They indicate their suppliers as three EU based plasticiser producers, which have all positively replied for this study that they at present have no manufacture of DHNUP. The reason for this discrepancy is not known. Among possible explanation may be that the cable producer uses stock bought in previous years, or that some of the manufacturers do not currently produce DHNUP, but have the equipment needed for the manufacture, and the ability to manufacture DHNUP upon request.

The use of DHNUP is registered in Product Registers for Denmark and Sweden (reference is made to appendix 1). In Denmark a consumption of 1 tonne/year has been registered for 2004 and 2005 for the product group "adhesives and binding agents", while a consumption of 0.1 tonne/year for 2004 and 2005 has been registered for the product group "paint, lacquers and varnishes". In Sweden consumption of 2 tonnes/year has been registered for 2006 - 2008 for the product group "construction materials". In this context the term construction materials probably covers sealants or adhesives. In Sweden, furthermore, a significant consumption of 377 tonnes/year was registered for the product group "softeners" in 2001, but no consumption for this product group has been registered since 2002.

DHNUP is included in Annex II (substances which must not form part of the composition of cosmetics products) to the EU Cosmetics Directive (76/768/EEC).

DHNUP was pre-registered under REACH with indication of registration by 30 November 2010. However, the substance does not seem to have been registered.

No other information of manufacture, import, exports and uses of DHNUP in the EU is available.

From an assessment undertaken by Environment Canada/Health Canada [Environment Canada 2009] it is known that:

DHNUP was reported to be manufactured in Canada at a quantity of 100 - 1,000 tonnes in 2006. Import of DHNUP to Canada (whether alone, in a mixture, in a product or in manufactured items above the reporting threshold of 100 kg) was reported at a quantity of 10,000 - 100,000 tonnes in 2006. Available information indicates that manufacture (in Canada) has decreased significantly since 2006 and that import to Canada has decreased by more than 90%. The decrease is mainly due to increased cost of raw materials. The long-term trend is unknown, but may depend upon the development of the cost gap between linear and branched plasticiser alcohols [Environment Canada 2009].

DHNUP is in Canada used principally for plasticiser applications and mainly as a plasticiser to PVC [Environment Canada 2009].

From [ITK 2010] it is known that:

In Canada, DHNUP is used in polyvinyl chlorides (PVC) and foam; automotive sealant; urethane, glass, and transmission adhesive; roof coatings, barrier coatings, exterior trim, and tarps; cement, caulk, and sealer; and high-end luggage. After 2006, the use of DHNUP is mainly in the plasticization of electrical and communication wire insulation.

The high consumption figures available for Canada raises the question whether significant import of DHNUP may take place with finished goods imported to Europe. While dominant products as electrical wires are not likely to be imported between continents, it cannot be ruled out that DHNUP could be present e.g. as sealants in cars imported to the EU. No information, however, has been available on this issue.

2 CURRENT KNOWLEDGE ON ALTERNATIVES

No information on alternatives has been given by any of the data sources contacted for this study. The only user of DHNUP registered has not replied to any of the questions in the downstream user questionnaire regarding alternatives, except for stating that they are not currently doing work into alternatives. All other data sources have replied that they do not use DHNUP, or have no information about the usage, and probably therefore no information has been given on alternatives either.

DHNUP is a mixture of high-medium weight, high solvating ortho-phthalates and high weight, low migration ortho-phthalates. Based on background knowledge on the mechanisms of plasticisers used in PVC, this likely means that DHNUP gives higher speed processing (fusing/gelation), and perhaps at lower processing temperatures than high weight phthalates alone. At the same time, the high-weight constituents lower the potential for evaporation and migration of the plasticiser out of the finished flexible PVC product, which is a desirable characteristic especially for high temperature applications such as cables. When a cable is used, the temperature in the insulation/sheathing rises, and low-medium weight plasticisers would tend to evaporate. Over the years this would result in reduced flexibility of the insulation layer with a risk of crack formation and accidents with the electricity. Similarly for sealants, it may be the case that the high weight plasticisers will migrate less into adjacent materials and evaporate less and thus help preserve the flexibility of the sealant over longer time. The flexibility and the adhesion keep the seals tight.

The currently dominant plasticisers in the EU, the ortho-phthalate mixtures DIDP and DINP, however have similar characteristics, as they are also mixtures of low-medium and high weight plasticisers. The dominant plasticiser in cable and wire production on the EU today seems to be DIDP [Maag *et al* 2010b], which is the heavier of the two mixtures, but also DINP and DEHP are used.

Examples of ortho-phthalate alternatives to DHNUP

DINP, di-isononyl phthalate has the CAS numbers 28553-12-0 and 68515-48-0. DIDP, di-isodecyl phthalate has the CAS numbers 26761-40-0 and 68515-49-1.

The substitution of DEHP with DINP or DIDP generally only requires a reformulation of the polymer/plasticiser mixture used, perhaps supplemented with minor process adjustments such as adjusting the process temperature or the process speed. Based on our background information, these are generally not major changes requiring physical changes in the production equipment. The same is expected to be the case when substituting DHNUP with for example DIDP, except that these substance mixtures are deemed closer to each other and therefore likely demanding less change.

The fact that DIDP is the dominant plasticiser in PVC insulated cables in the EU makes it likely that DIDP may actually be a more cost effective solution than DHNUP seen over the product life cycle. Also, it is not uncommon to hear among industry contacts that classification of chemicals makes users seek technically suitable alternatives.

As we do not have any indications of the sale of DHNUP in the EU, we also do not have any indications of possible cost differences between DHNUP and alternatives.

The widespread use of DIDP and DINP, the (slightly outdated) information that the prices of these phthalates were around 2006 only slightly above the price for the previous standard phthalate DEHP, and the industries' explicit preference for DINP and DIDP above non-ortho-phthalate alternatives could all be seen as possible indication that DINP and DIDP are available in adequate amounts on the market (prices: [TURI 2006]).

DTDP (1,2-Benzenedicarboxylic acid, di-C11-14-branched alkyl esters, C13-rich; CAS 68515-47-9) is another ortho-phthalate which has been mentioned as a specialty plasticiser for high temperature cable and wire, and for automotive cable applications. Due to its high molecular weight, its vaporisation and migration out of the polymer are minimal compared to other ortho-phthalates. It is manufactured by ExxonMobil (possibly among others) and marketed under the trade name Jayflex DTDP [ECPI, 2011; ExxonMobil, 2011].

911P (1,2-Benzenedicarboxylic acid, di-C9-11-branched and linear alkyl esters; CAS 68515-43-5) may also be a possible plasticiser for cable and wire use, as well as for low-fogging (low evaporation) PVC parts in automotive industry. It is a medium weight ortho-phthalate plasticiser, manufactured by BASF (among others) who market it under the trade name Palatinol 911P. It is suggested by the manufacturer for use in sheeting, film extrusion, and vinyl dispersions where good low temperature properties are required and where low volatility ensures a greater permanence [BASF, 2011].

Another example of an ortho-phthalate plasticiser suggested by the manufacturer for use in sealants is 1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters (CAS No. 68515-40-2;). It is a medium-weight plasticiser manufactured by Ferro (possibly among others) and marketed under the trade name Santicizer® 261 Plasticizer. According to Ferro, it finds application in polyurethane and polysulfide caulks and sealants, film and sheeting, coated fabrics, PVC plastisols, organosols, vinyl foams and acrylic lacquers [Ferro 2011].

Examples of non-ortho-phthalate alternatives

Also low-migrating and low-evaporating non-orthophthalate plasticisers are available on the market. Their use is however currently less widespread than that of the ortho-phthalates on the EU market. Factors influencing this may be less practical experience with these alternatives, or the higher prices for some of these. Some examples (among many) of such possible non-orthophthalate alternatives are mentioned below:

- TOTM (tri-ethyl-hexyl-trimellitate, also called tri-octyl-trimellitate, CAS no. 3319-31-1). High weight, low migration, low evaporation specialty plasticiser used for such purposes as

cables. Commercially matured. Some environmental issues have been identified [Maag *et al* 2010a].

- DEHT (di-ethyl-hexyl-terephthalate, also called DOT, CAS no. 6422-86-2. A general purpose plasticiser with prices near DEHP, DINP and DIDP, so far used more in North America than in the EU. Somewhat lower molecular weight than DIDP and DINP. Commercially matured with significant experience in cable and sealant applications. Better environmental characteristics than its isomer DEHP [Maag *et al* 2010a].
- COMGHA (CAS no. for mixture: 736150-63-3). General purpose plasticiser derived from castor oil. Prices significantly higher than the general plasticiser DEHP and currently with limited availability. Commercially available, but limited experience in cable and sealants applications [Maag *et al* 2010a].

2.1 Conclusions for alternatives

Alternatives to DHNUP are commercially available and seem to have almost substituted for DHNUP in EU production already (as only one example of DHNUP usage was identified). The key alternatives to DHNUP appear to be relatively well described as regards technical characteristics, though for some of them, the environmental characteristics are not quite as comprehensively described as for traditional phthalate plasticisers such as DEHP, DINP and DIDP.

In the flexible PVC sector, there is a tradition for cooperation between plasticiser suppliers and producers of PVC products in selecting suitable plasticisers for the specific production, in adjusting polymer formulations, etc.

References

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TURI 2006. Five chemicals study. Toxics Use Reduction Institute (TURI), University of Massachusetts Lowell, for the Commonwealth of Massachusetts. Chapter on alternatives to DEHP available at: http://www.turi.org/library/turi_publications/five_chemicals_study/final_report/chapter_7_dehp#7.

APPENDIX 1: DATA FROM THE NORDIC PRODUCT REGISTERS

Data from the Nordic product registers were retrieved from the SPIN database as part of the data collection process. Product registers exist in Norway, Denmark, Sweden and Finland. (SPIN website: <http://195.215.251.229/DotNetNuke/default.aspx>).

The substances covered by the product registers differ among the countries. A brief description is presented below as background for the interpretation of the data.

Substances covered by the product registers

In Sweden the declaration requirements are based on the customs tariff codes, so that as a general rule they apply to all chemical products (substances and preparations). The Swedish register therefore contains more products than those that are classified as dangerous according to EU legislation. In Sweden, substances that are not classified as dangerous and that make up less than 5 per cent of a product may be omitted from the declaration.

In Norway, declaration is mandatory for all products to which the Regulations relating to the classification, labelling, etc. of dangerous chemicals (the Chemical Labelling Regulations) apply. These regulations implement EU legislation on the classification, labelling, etc. of chemicals in Norwegian legislation. It means that declaration is only mandatory for products in which one of the substances is included in the list of dangerous substances. For declared products all constituents of the product is registered, irrespective of whether the substances are included in the list of dangerous substances.

In Denmark, like in Norway, the declaration is mandatory for products including dangerous substances, but the requirements also apply to all solvents, pesticides, biocides and cosmetics. Information on all constituents is required for products for which declaration is mandatory. Denmark has complete information on composition for the majority of products. Until 2004 declaration was not mandatory for products marketed before April 1983, and for this reason e.g. fuels were generally not declared.

In Finland, like in Norway and Denmark, the declaration is mandatory for products including dangerous substances. Additional requirements apply to pesticides and chemicals that cause danger, although they are not classified. The information on the composition of products is registered from the safety data sheets. Complete information on the exact composition is consequently not necessarily given. There are no data from Finnish reports in these tables, noted for each relevant product group as "n.a." (Not available).

Exemptions

All four countries exempt products that fall under the legislation on foodstuffs and medicinal products from mandatory declaration. Furthermore, the duty to declare products to the product registers does not apply to cosmetic products in Sweden, Norway and Finland. There is also a general exemption from the duty to declare chemicals in Sweden, Finland and Norway, if the quantity produced or imported is less than 100 kg per year. This means that small volumes of chemicals (e.g. laboratory chemicals or pharmaceuticals) may escape registration.

In addition, there is no requirement to declare articles to any of the registers. Thus, the duty to declare products to the registers does not include chemicals in textiles, chipboard, etc.

Update of product register data

In Sweden and Norway the quantities, the classification, the codes for areas of use and the codes for product types of products are updated every year, and trends can therefore be followed for both substances and products.

Updating of the other information given by the company at registration, such as composition and physical properties, is supposed to take place whenever these conditions are altered.

In Finland the quantitative data are quite up-to-date as the Finnish product register has only been collecting information on quantities since year 2001.

In Denmark, there is no systematic updating of quantities of products. The companies are obliged to send in any new information regarding their products whenever changes occur. If companies fail to fulfil their obligations, a result might be that products that have been discontinued still remain on the lists. For the present analysis the Danish product register has contacted companies who have declared the use of the substances and updated the declared quantities on this basis.

Registered consumption

The registered consumption of DHNUP in the Nordic product registers is shown in Table A3-1, and Table A3-2 below. The registers in Norway, Denmark and Finland mainly include products containing dangerous substances.

Denmark and Sweden are the only countries reporting use of DHNUP in 2000-2008.

Table A3-1 Use Category UC62 of 1,2-Benzenedicarboxylic acid, di-C_{7,11}-branched and linear alkyl esters (DHNUP) in Products in Denmark

Denmark Category UC62 Product group	2005 t/y	2004 t/y	2003 t/y	2002 t/y	2001 t/y	2000 t/y
Adhesives, binding agents	1.0	1.0	0.1	0.1	0.0	0.2
Paints, laquers and varnishes	0.1	0.1	0.0	0.0	-	-

Note: - : no reported use

Table A3-2 Use Category UC62 of 1,2-Benzenedicarboxylic acid, di-C_{7,11} -branched and linear alkyl esters (DHNUP) in Products in Sweden

Sweeden Category UC62 Product group	2008 t/y	2007 t/y	2006 t/y	2005 t/y	2004 t/y	2003 t/y	2002 t/y	2001 t/y	2000 t/y
Construction materials	2.0	2.0	2.0	-	-	-	-	-	-
Softeners	-	-	-	-	-	-	-	377.0	190.0

Note: - : no reported use