Product Safety Assessment Report

Product name: Power code

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1. Preface

This article safety assessment report is prepared to supply the recipients with sufficient information to allow safe use of the article, containing SVHC (substances of very high concern identified according to Article 59(1) of Regulation (EC) 1907/2006 (REACH)) in concentrations exceeding 0.1 % w/w, according to Article 33 (Duty to communicate information on substances in articles) of REACH.

2. Basic information on the article

2.1 Product name

Power code (covered by PVC resin)

2.2 Name of the SVHC contained in the article and intended use

(1) Substance name: Bis(2-ethylhexyl)phthalate : DEHP

(2) Intended use: Plasticizer for the PVC resin

3. Information on the SVHC in the article

Substance name	Bis(2-ethylhexyl)phthalate, DEHP
CAS Number	117-81-7
EC Number	204-211-0
Classification	Human health: Toxic to reproduction, Category 2; R60-61
Concentration in the containing part of the article	20 w/w % (containing part; covering material)
Information on safe use	The risk of this article for human health is considered to be low. However, caution against long term continuous sucking especially by infants.

4. Detailed information on the SVHC[1)]

4.1 Identity of the substance

(1) Substance name: Bis(2-ethylhexyl)phthalate

(2) Synonyms: Di(2-ethylhexyl)phthalate

DEHP

Dioctyl phthalate (also be used for Di-n-octyl phthalate)

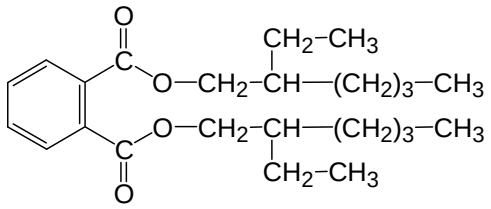
DOP (collective term incl. DEHP)

Di-sec-octyl phthalate

(3) CAS Number: 117-81-7

(4) Molecular formula and structural formula;

$C_{24}H_{38}O_4$



(5) Molecular weight: 390.56

4.2 Physico-chemical properties

(1) Appearance: Colourless viscous liquid

(2) Melting point: -55℃, -50℃

(3) Boiling point: 385℃

(4) Density: 0.984 g/cm^3 at 20℃, 0.986 g/cm^3 at 20℃

(5) Vapour pressure: 3.4 x 10 $^{-5}$ Pa at 20℃

(6) Water solubility: 0.0006 - 1.3 mg/L

(7) Surface tension: 32.2 mN m^{-1} at 20℃

(8) Flash point: 200℃

(9) Auto-ignition temperature: 350℃

(10) Explosive properties: 0.15-0.18 vol%, 0.3-49 vol%

(11) Relative density (water = 1): 0.986（IPCS2001）

(12) Relative vapour density: 13.46 (air=1)

(13) Hydrolysis: DEHP is hydrolyzed to phthalic acid and 2-ethylhexanol.

Estimated half-life time:5.3 years (pH7, 25℃)(HYDROWIN ver.1.67, US EPA,2004)

5. Risk assessment for human health

PVC resin, commonly used as the covering material for the power code, includes phthalates as plasticizer. Therefore, there is concern that phthalates may elute from the power code at concentrations more than the acceptable level amount for human health. In the present assessment, we conducted the risk assessment for human health caused by phthalates, which are contained in the power code covered by PVC resin.

5.1 Exposure assessment for human health (estimation for the extraction of phthalates)

Related to the effect of phthalates, contained in electronic equipments, on human health, several exposure scenarios are expected. The EU Risk Assessment Report[1)] suggested that the highest exposure results from toys and child-care articles. In addition, it concerned the increase of the extraction by "chewing" and considered it in the exposure estimation. Consequently, for the purpose of the present assessment, the following exposure scenario was considered.

Exposure scenario: Oral exposure of infants to DEHP caused by putting the power code into their mouths (mouthing) and chewing.

In the EU Risk Assessment Report[1)], no standard method to mimic the exposure during chewing was defined. Instead, the chewing method of the human subjects and the flask shaking extraction method were introduced.

Yamada et al.[2)] reported that in the extraction test using artificial saliva, placing the test vessel with glass beads resulted in 75% increase of the extraction amount compared with the case not using glass beads, and stable extraction amount was obtained. As this result showed the similar extraction amount to the result from the chewing test conducted in the human mouth, this method using the artificial saliva with glass beads is considered to be an appropriate method to mimic the exposure during chewing, which reflects the increase of the extraction by "chewing."

In the present assessment, the extraction of phthalates was estimated by the extraction test using artificial saliva with glass beads complying with the method proposed by Yamada et al. The test method and the results are as follows.

(1) Extraction test method and analysis method

Approximately 15 cm^2 (approx. 1 g) of the sample cut out from wire coating PVC was placed in an Erlenmeyer flask containing 30 mL of the artificial saliva (0.4 g of ammonium chloride, 0.3 g of sodium sulfate, 0.2 g of urea, and 3.0 g of lactic acid dissolved in 1 L of ion-exchanged water) with glass beads (10 mmφ). The flask was placed in a 37℃ oven and shaken for 15 min (horizontal shake, shaking rate: 120 cycle/min, travel distance: 40 mm). After removing the eluent, 30 mL of the artificial saliva was newly added and shaken for 15 min again. This procedure was repeated 4 times

(total extraction time: 60 min). Eluent obtained from the fourth procedure was mixed and employed for hexane extraction-gas chromatography/mass spectrometry (GC/MS).

(2) Result of the extraction test

PVC, used as the covering material for the power code in our products, was employed to the abovementioned extraction test. The following table presents the results of the analysis of the extracted phthalate. The extracted amount of DEHP was converted to the amount per 10 cm^2 in 1 h (60 min) on the basis of the research report "Exposure estimation of DEHP or DINP migrated from toys" (Food Sanitation Investigation Council of Health, Labour and Welfare Ministry, Japan).

Table The results of the extraction test

DEHP extraction amount

Plasticizer / Sample	DEHP		
PVC cover material for the power code	< 0.8μg/h	< 0.8μg/h	< 0.8μg/h

The results of the extraction test (n = 3) indicated that, the extraction amount of DEHP was below the detection limits.

5.2 Hazard assessment for human health

Regarding the effect of DEHP caused by inhalation exposure, increased incidence of neuropathy was reported in groups occupationally exposed to several phthalates, including DEHP. However, the association is considered questionable due to the lack of a control group and presence of other exposure components (phthalic anhydride and respective alcohols) that could have caused this effect (Dutch Expert Committee on Occupational Standards, 1994).

In preterm infants, artificially ventilated with PVC respiratory tubes, decease caused by lung disorder were observed during the fourth week of life in three infants and suggested that inhalation of DEHP may concern (Roth et al., 1998). On the other hand, Health Canada pointed out the over estimation of the exposure concentration (Health Canada, 2002). In addition, FDA suggested that the correlation between inhalation of DEHP and lung disorder were suspicious (FDA, 2001).

No human data relevant for the risk assessment is obtained via oral or dermal route.

Because limited human data is available on the effect of DEHP, hazard assessment is conducted on the basis of animal testing data. The following table shows the toxicity data of DEHP employed for risk assessment in the EU Risk Assessment Report[1)].

Table Toxicity data of DEHP employed for risk assessment in the EU Risk Assessment Report[1)]

Species	Test method	Effects observed at LOAEL	LOAEL	NOAEL
Repeated-dose toxicity				
Rat, F344	Diet, 2 years	Increase of absolute and relative kidney weight	147 mg/kg/day	29 mg/kg/day
Reproductive toxicity				
Rat, SD	Diet, 3-generation	Testicular toxicity	14 mg/kg/day	4.8 mg/kg/day
Mouse, CD-1	Diet, Continuous breeding study	Decrease of fertility and proportion of live pups	200 mg/kg/day	20 mg/kg/day

5.3 Risk Characterization for human health

In the present assessment, Risk Characterization Ratios (RCR) was employed as an index for risk characterization.

$$RCR = \frac{\text{Exposure}}{\text{DNEL}}$$

In the above equation, Derived No-effect Level (DNEL) means the estimated No-effect Level, which derived by dividing NOAEL by Assessment Factor (AF). AF is the corrective coefficient established by taking into account (a) the uncertainties arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation; (b) the nature and severity of the effects; (c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies.

Whether the risk is adequately controlled or not is evaluated by the RCR value. If RCR < 1 (i.e. Exposure < DNEL), the risk can be considered to be adequately controlled. On the other hand, if RCR > 1 (i.e. Exposure > DNEL), the risk is NOT controlled.

RCR > 1	Risk is NOT controlled
RCR < 1	Risk is adequately controlled

Here, RCR can be derived from the equation below by using the extraction amount of phthalates.

$$RCR = \frac{\text{extraction amount (μg/h)} \times \text{mouthing time (h/day)} / \text{body weight (kg)}}{\text{NOAEL (μg/kg/day)} / \text{AF}}$$

Risk for human health caused by DEHP extracted from PVC covering material for power code was characterized using the above equation. Based on data reported in "Draft interim report from investigation committee on handling of toys containing phthalates,"[4] the maximum value obtained from video recording of one-day behavior of infants aged 6–10 months was used as the mouthing time, and the average body weight of infants aged 3–10 months was used as the body weight in the calculation. For deriving DNEL, the minimum NOAEL reported in the EU Risk Assessment Report[1] and the maximum AF derived on the basis of the ECHA guidance document[5] were used to get a result standing on the safe side, which reflects the expected worst-case scenario.

Calculation parameters

Extraction amount: < 0.8μg/h

Mouthing time: 136.5 min/day (maximum value)[4]

Average weight of infants: 8.37kg[4]

NOAEL[1]: 4.8mg/kg/day (SD rat)

AF[5]: 240 (=4×10×6)

(Interspecies differences: 4 (Rat), Intraspecies differences: 10,
differences in duration of exposure: 6)

The result of the calculation using the equation and parameters mentioned above show that RCR was less than 0.011. Consequently, the risk for infants caused by mouthing power code is considered to be low and to be adequately controlled.

6. Conclusion

In this assessment report, the risk for oral exposure of infants to DEHP caused by mouthing power code was evaluated by means of RCR. The derived RCR was low (<0.011); even the maximum exposure-time based on the worst case scenario was applied, whereas if RCR is less than 1, the risk is considered to be adequately controlled. This result shows that the risk for oral exposure to DEHP can be considered to be low.

References

1) EC2008 Bis(2-ethylhexyl)phthalate（DEHP）. Europian Union Risk Assessment Report. Vol.80. http://ecb.jrc.it/existing-chemicals

2) Research report on release of endocrine disrupters from food and food packages.(National Institute of Health Sciences, Japan) http://www.nihs.go.jp/edc/houkoku10/10-7/10-7-index.htm

3) Exposure estimation of DEHP or DINP migrated from toys. (Health, Labour and Welfare Ministry, Japan) http://www.ffcr.or.jp/zaidan/MHWinfo.nsf/0f9d5ee834a5bcff492565a10020b585/e4fb55ed0745ee7549256ab500228013?OpenDocument

4) Draft interim report from investigation committee on handling of toys containing phthalates (Health, Labour and Welfare Ministry, Japan) http://www.mhlw.go.jp/shingi/2009/02/dl/s0213-10h.pdf

5) Guidance on Information Requirements and Chemical Safety Assessment Chapter R.8: Characterisation of dose [concentration]-response for human health http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r8_en.pdf?vers=20_08_08