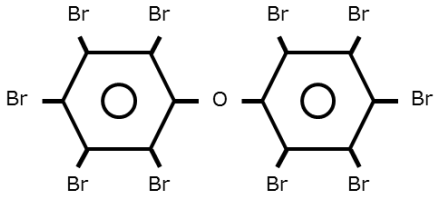
June 2018
Edited by NITE

Risk assessment for chemical substances contained in products

Decabromodiphenyl ether: Summary

Profile of the target substance

CSCL number	3-2846
CSCL name	Decabromodiphenyl ether
CAS_RN	1163-19-5
Molecular formula	$C_{12}Br_{10}O$
Structural formula	

In September 2000, decabromodiphenyl ether was classified as a designated chemical substance, which means it is "suspected to be a chemical substance (Class II Specified Chemical Substance) that is not high bioaccumulative but non-readily degradable and has long-term toxicity" under the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture etc. (Chemical Substances Control Law: CSCL). It was designated as a Type II Monitoring Chemical Substance at the time of the amendment to the CSCL in 2003. In the amendment of the CSCL in 2009, it became a general chemical substance based on the screening assessment result. At the conference of the parties to the Stockholm Convention on Persistent Organic Pollutants in May 2017, it was decided that decabromodiphenyl ether be added to the substances to be eliminated or restricted. In July 2017, it was judged to be appropriate to designate decabromodiphenyl ether as a Class I Specified Chemical Substance under the provision in Article 2, paragraph (2) of the CSCL because it is highly bioaccumulative, not readily degradable, and also has long-term toxicity.

Decabromodiphenyl ether (BDE-209)[1], which is the subject substance of this risk assessment, is mainly used as flame retardant for resin and textile, and is contained in consumer products such as electrical appliances, plastic products, and car seats. The National Institute of Technology and Evaluation (NITE) conducted the risk assessment on the health effects for Japanese people who are exposed to BDE-209 via those products indoors and in a car interior.

Based on usage information in the investigation and notifications based on the CSCL, the results of an investigation of actual concentrations in Japan conducted by the Ministry of Economy, Trade and Industry (METI), and the data of risk assessments conducted in foreign countries, furniture, car fabrics, and indoor and car-interior dust, by which Japanese people

[1] Commercial decabromodiphenyl ether (c-decaBDE) is a synthetic mixture of polybrominated diphenyl ethers, with the main component being the fully brominated congener decaBDE (BDE-209). In this report, the risk of BDE-209 is assessed.

might be exposed to the substance in relatively high concentrations among the products that Japanese people use in their homes or cars, were set as the exposure sources to be investigated.

Adults and children under the age of 6, living in Japan, were set as the target groups of people in this risk assessment. The reason why the assessment was conducted so as to include young children was that their intake through mouthing behaviors such as holding objects in their mouth and licking objects or through dust is different from the intake of adults.

Hazard assessment

In the hazard assessment report on polybrominated diphenyl ether issued by the Agency for Toxic Substances and Disease Registry (ATSDR) in March 2017, a Minimal Risk Level (MRL) of 0.2 μg/kg/day has been derived for an intermediate-duration oral MRL for BDE-209 as part of information on exposure. Use of the MRL in this risk assessment was first examined. The ATSDR, however, has only derived the MRL for intermediate-duration exposure, due to insufficient data on a chronic-duration oral MRL. Therefore, the MRL was derived based on a LOAEL of 0.05 mg/kg/day for the intermediate-duration oral MRL in order that it could be used as a hazard assessment value for chronic-duration exposure based on intermediate-duration oral MRL estimated by the ATSDR. The intermediate-duration oral MRL estimated by the ATSDR was derived by dividing the LOAEL value by an uncertainty factor of 300 (10 for animal-to-human extrapolation, 10 for human variability, and 3 for use of the LOAEL). In consideration of the uncertainty about the test period as well, a hazard assessment value of 0.05 μg/kg/day (50 ng/kg/day) was derived by dividing the LOAEL of 0.05 mg/kg/day by an uncertainty factor of 1000 (10 for animal-to-human extrapolation, 10 for human variability, and 10 in consideration of the use of LOAEL as well as the test period). For this risk assessment report, it was decided that this value should be used as the hazard assessment value for chronic-duration exposure.

Exposure assessment

For the estimation of the exposure amount, eight exposure scenarios in total were set for each environment (inside houses and cars) where the products to be investigated are used or exist, and the estimation equations according to the exposure scenarios and the parameters required for the estimated equations were set. It was finally decided that the e*stimated human exposure (EHE)* per day be calculated by summing the exposure amount estimated for each of the eight exposure scenarios.

The exposure scenarios and parameters were set according to the environment where the products to be investigated are used or exist or the use conditions of the products. In setting the parameters, a strict condition that the exposure amount be overestimated by a reasonable amount was adopted. Therefore, the *EHE* is calculated with this strict condition in force in most

scenarios and parameters. Each parameter was set based on investigation results reported in the existing literature. For the parameters on which there was insufficient information or an insufficient check of validity of results, tests of products containing BDE-209 were conducted at the NITE Product Safety Technology Center and Hokuriku Regional Office and the results were also used.

As the results of the exposure assessment, the *EHE* was 20.4 ng/kg/day for adults and 131.9 ng/kg/day for children. In the environments inside houses and cars, the exposure amount by oral intake of BDE-209 absorbed dust released from the products was far larger for both adults and children than that by the direct intake using the products containing BDE-209, making up 97% of the *EHE*

Table 1 *Estimated human exposure* of BDE-209 inside houses (ng/kg/day)

exposure route	exposure scenario	adults		children	
inhalation		0.34		0.49	
oral	ingestion of dust	5.9	5.9	38.5	39.3
	mouthing	—		0.81	
dermal		0.07		0.10	
EHE inside houses		adults		children	
		6.3		39.9	

Table 2 *Estimated human exposure* of BDE-209 inside cars (ng/kg/day)

exposure route	exposure scenario	adults		children	
inhalation		0.16		0.23	
oral	ingestion of dust	13.6	13.6	89.5	89.6
	mouthing	—		0.09	
dermal		7.4×10^{-3}		0.011	
EHE inside cars		adults		children	
		13.8		89.8	

$$EHE\ averaged\ over\ a\ lifetime = \frac{Daily\ intake\ for\ children \times 6\ years + Daily\ intake\ for\ adults \times 64\ years}{Human\ lifetime\ (70\ years)}$$

Table 3 Total *estimated human exposure* of BDE-209 (ng/kg/day)

exposure route	*EHE* over a lifetime
inhalation	0.52
oral	28.9
dermal	0.08
total *EHE*	29.5

Risk assessment

In the risk assessment, the *Hazard Quotient (HQ)* was obtained by dividing the *EHE* by the hazard assessment value, and it was decided that if the *HQ* was 1 or larger, then the risk is at a level of concern, and if the *HQ* was less than 1, then the risk is not at a level of concern.

In the risk assessment, considering that the hazard assessment value is a chronic-duration value, the respective *EHE* for adults and children were calculated in the exposure assessment, so those amounts were converted into the average exposure amount over a life-span of 70 years, from birth to adulthood (weighted average exposure amount in 70 years).

As a result of the risk assessment, for a chronic duration, the hazard assessment value was 50 ng/kg/day, while for the lifetime average exposure amount was 30 ng/kg/day, indicating a *HQ* of 0.6, which is below 1. Therefore, it is considered that even in the case of the results obtained applying multiple instances of the abovementioned strict condition under which the exposure amount is overestimated by a reasonable amount, the risk is not at a level of concern.

According to the exposure amount per day in childhood, the *HQ* would be 1 or higher. However, it is not appropriate to simply use the hazard assessment value for chronic-duration exposure, and it is considered better to use the intermediate-duration oral MRL derived by the ATSDR. Also in this case, the *HQ* is 0.6, which is not at a level of concern.

$$HQ = \frac{EHE\ averaged\ over\ a\ lifetime}{Hazard\ assessment\ value} = \frac{29.5\ \text{ng/kg/day}}{50\ \text{ng/kg/day}} = 0.6$$

EHE over a lifetime:	29.5 ng/kg/day
Hazard assessment value:	50 ng/kg/day
HQ:	0.6

Risk management

BDE-209 was designated as Class I Specified Chemical Substance under the CSCL. Therefore, import, manufacture, and sale of products containing BDE-209 are prohibited, and it is expected that the exposure amount will become smaller than the *EHE* in this risk assessment in the future. Furthermore, even if products containing BDE-209 that are currently used or placed inside houses and cars continue to be used in the future, the risk to human health due to the products is considered not to be at a level of concern.

It is considered that replacement with other flame retardants or change of specifications will be conducted in the future, but in that case, the replacement may introduce new risks. This is called an antimony issue or risk trade-off.

In order to prevent product accidents associated with the chemical substance control, it is necessary to properly transmit the information on replacement of BDE-209 with other substances or change of specifications to the manufacturers, to conduct thorough verification

and assessment not only of the risk from the chemical substances but of the risk of product accidents and to pay attention to the risk trade-offs.