

AGREEMENT OF THE MEMBER STATE COMMITTEE  
ON THE IDENTIFICATION OF  
BUTYL 4-HYDROXYBENZOATE (BUTYLPARABEN)  
AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59 of  
Regulation (EC) 1907/2006<sup>1</sup>

Adopted on 28 May 2020

This agreement concerns

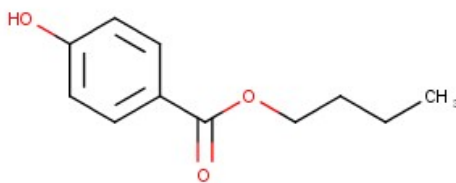
Substance name: Butyl 4-hydroxybenzoate (Butylparaben)

EC number: 202-318-7

CAS number: 94-26-8

Molecular formula: C<sub>11</sub>H<sub>14</sub>O<sub>3</sub>

Structural formula:



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<sup>1</sup>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Denmark presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (25 February 2020) on identification of *Butyl 4-hydroxybenzoate (Butylparaben)* (EC No. 202-318-7) as a substance of very high concern due to its endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those of other substances listed in paragraphs (a) to (e) of Article 57 of REACH Regulation.

The Annex XV dossier was circulated to Member States on 3 March 2020 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 18 May 2020 and agreed in the written procedure of the Member State Committee with closing date of 28 May 2020.

Agreement of the Member State Committee in accordance with Article 59(8):

*Butyl 4-hydroxybenzoate (Butylparaben)* is identified as a substance meeting the criteria of Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because it is a substance with endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those of other substances listed in paragraphs (a) to (e) of Article 57 of REACH Regulation.

## UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN

Endocrine disrupting properties - Article 57(f):

Butyl 4-hydroxybenzoate (butylparaben) is identified as a substance of very high concern in accordance with Article 57(f) of Regulation (EC) 1907/2006 (REACH) because of its endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health which gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 REACH.

Endocrine disrupting (ED) properties of butylparaben relevant for human health:

The adverse health effect is reduced sperm count and quality (number of normal sperm) as observed in rodent studies using perinatal exposure. These effects are considered severe as similar effects in humans could cause sub- and infertility. Effects are irreversible and are shown to occur later in life after exposure in the perinatal period only. There is supportive evidence from studies on adverse effects on sperm count and quality in rodents following pubertal and/or adult exposure, although there are some inconsistencies between these studies.

There is sufficient evidence to conclude that butylparaben acts via endocrine mode(s) of action according to a mode of action analysis including an evaluation of biological plausibility. The evidence is strongest for estrogenic activity shown *in vitro* and *in vivo*, but some studies also point to altered steroidogenesis and androgen receptor (AR) antagonism.

Based on the above conclusion, evidence that the substance is of an equivalent level of concern includes:

Sub- and infertility are not only detrimental to the propagation of the species, but also have a major impact on quality of life. Fertility treatment and counselling carry high societal costs.

No safe concentration/level can be derived from the available data on adverse reproductive effects via endocrine modes of action. Two of the available studies show reduced sperm count or quality in perinatally exposed rats at the lowest tested dose, and no NOAEL can be determined for this endpoint.

Therefore, it is concluded that the substance *Butyl 4-hydroxybenzoate (Butylparaben)* meets the criteria of Article 57(f) of REACH, due to its endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those for other substances listed in paragraphs (a) to (e) of Article 57 of REACH Regulation.

Reference:

Support Document (Member State Committee, 28 May 2020)