Substance name: **BIT**; 1,2-benzisothiazol-3(2H)-one; 1,2-benzisothiazolin-3-one

CAS Number: 2634-33-5

EC Number: 220-120-9

Table 1: Studies, which shows that BIT causes skin sensitization

| Study | Type | Reliability* | $EC_3$ | Conclusion |
|---|---|---|---|---|
| | | | | |
| *Anonymous*, 2007<br>IIIA6.1.5/01<br>**KEY STUDY*** | LLNA | 1 | $EC_3$ = 29%<br>$EC_3$ = (technical) = 25.8% | Skin Sens. 1B |
| *Anonymous*, 2007<br>IIIA6.1.5/02<br>**KEY STUDY*** | LLNA | 2 | $EC_3$ = 1.54% | Skin Sens. 1A |
| *Gerberick et al.*, 2005 in Dermatitis (4):157-202 | LLNA | | $EC_3$ = 2.3% | Skin Sens. 1B |
| *Basketter et al.*, 1999 in Contact dermatitis 40(3):150-154 | LLNA | | $EC_3$ = 10.4% | Skin Sens. 1B |
| *Anonymous*, 1991<br>TC C&L document | LLNA | | - < 10%: no effect<br>- 10%: significant in 1 of 2 experiments<br>- 50%: significant in 2 of 2 experiments | Skin Sens. 1B |
| *Botham et al.*, 1991 in Contact Dermatitis 25(3):172-177 | LLNA | | $EC_3$ = 4.8%<br>$EC_3$ = 32.4% | Skin Sens. 1B |
| *Anonymous*, 2003<br>IIIA6.1.5/2 | GPMT | 1 | | - |
| *Anonymous*, 2002<br>IIIA6.1.5/1<br>**KEY STUDY*** | GPMT | 2 | | Skin Sens. 1B |
| *Anonymous*, 1994<br>REACH registration dossier<br>**KEY STUDY*** | GPMT | 1 | | Skin Sens. 1B |
| *Anonymous*, 1990<br>REACH registration dossier<br>IIIA6.1.5/1<br>**KEY STUDY*** | GPMT | 2 | | Skin Sens. 1A |
| *Anonymous*, 1984<br>TC C&L document | GPMT | | | - |

***according to DoC IIA or DoC III of the active substance evaluation documents as prepared by ES

Table 2: Studies with human data, regarding possible sensitizing effects.

| Type of study | Number of cases | positive (%) | *Frequency* (according to CLP) | Reference |
|---|---|---|---|---|
| **General population studies** | 0/54<br>5/58 | 0,00<br>9.26 | -<br>**High** | *Basketter et al.*, 1999 |
| | 2/111 | 1.8 | **High** | *Plaza and Rheins*, 1991 |
| | 5/50 | 10 | **High** | *Davies et al.*, 1975 |
| | **12/273** | **4.4** | **High** | |
| **Dermatitis patients** | 20/2264 | 0.88 | **Low/moderate** | *Aalto-Korte et al.*, 2007 |
| | 10/556 | 1.8 | **High** | *Damstra et al.*, 1992 |
| | 1/404<br>1/466 | 0.25<br>0.22 | **Low/moderate**<br>**Low/moderate** | *Andersen & Hamann*, 1984 |
| | 55/997 | 5.6 | **High** | *Ledieu et al.*, 1991 |
| | 14/1652 | 0.9 | **Low/moderate** | *Andersen & Veien*, 1985 |
| | **101/6339** | **1.59** | **High** | |
| **Work place, selected** | 1/1<br>4/17 | 100<br>23.5 | **High**<br>**High** | *Damstra et al.*, 1992 |
| | 4/8 | 50 | **High** | *Díaz et al.*, 1992 |
| | 1/1 | 100 | **High** | *Sanz-Gallén et al.*, 1992 |
| | 48/230 | 20.90 | **High** | *Alomar et al.*, 1984 |
| | 1/1 | 100 | **High** | *Foussereau et al.*, 1984 |
| | 1/1<br>1/10 | 100<br>10 | **High**<br>**High** | *Freeman*, 1984 |
| | 4/20 | 20 | **High** | *Alomar*, 1981 |
| | 3/3 | 100 | **High** | *Roberts et al.*, 1981 |
| | 7/11 | 64 | **High** | *Slovak*, 1979 |
| | 1/1 | 100 | **High** | *Brown*, 1979 |
| | 2/2 | 100 | **High** | *Pedersen*, 1976 |
| | **78/306** | **25.5** | **High** | |