



DRAFT
SUMMARY RECORD
Meeting of the Commission Working Group on the
Classification and Labelling of Dangerous Substances

ECB Ispra, 1st - 3rd July 1998**Extract from Summary Record of the Commission Working Group on Classification and Labelling - CMR, October 1997:****Cobalt (II) chloride (W004) (CAS No. 7646-79-9, EC No. 231-589-4).****Proposal: [Carc. Cat. 2; R45] : [Xn; R22] : [Xi; R37] : [R42/43] : N; R50-53.****[Specific concentration limit for carcinogenicity: 0.01%]**

XI/393/93 - Add. 9	Ch. Arvius, EFTA - 14.3.94 classification proposals for W003, W004
XI/393/93 - Add. 24	EUROMETAUX, Cobalt and Carcinogenicity
XI/393/93 - Add. 29	UK HSE, Toxicity review 29 Cobalt and cobalt compounds
ECBI/26/95 - Add. 23	N, comments on classification of W003 & W004
ECBI/26/95 - Add. 24	DK, epidemiology studies of cobalt exposed women.

Cobalt sulphate and cobalt chloride are problematic for **S** (Accession Treaty) and **N** (EEA). Classification of both salts as **N**; R50-53 was agreed in April 1995. In October 1994, the **Group** discussed the classification proposal and agreed to postpone further discussion until results of the NTP study were available.

The **Group** agreed to classify cobalt chloride with Carc. Cat. 2; R45: Xn; R22 and R42/43. In the discussion on the lower limit for potency, there was less support for the 0.01 % limit proposed by **N**. At issue was as suggested by **CEFIC**, if the cobalt ion was to be considered. According to **N**, they had used the same arguments as for the nickel compounds, hence the cobalt ion was the assumed species so whether the compound was sulphate or chloride was immaterial. The **UK** were unhappy to draw an analogy from the sulphate to the chloride in this manner without the **Group** first deciding on the boundaries for SAR. Without doing this, the **Group** were stating that all soluble cobalt compounds should be treated in the same way. **In the absence of scientific fact or documentation, this was not possible.** **DK** and the **NL** could accept the necessity of drawing such analogies between the two substances. **CEFIC** stated that one could assume that cobalt chloride was carcinogenic by comparison with cobalt sulphate on the basis of the cobalt ion. **However as there was no animal data for the chloride, there was no possibility to generate the T₂₅ and hence no specific limit should be applied for this substance.** **IRL** expressed sympathy with this view as they too were unhappy in taking some doses from the sulphate to the chloride especially as irritation was a possible cause. The **UK** suggested that a possible solution would be to apply the standard concentration limit for R45 to both the chloride and sulphate without Nota 1 which would provide a limit of approximately 0.04 %. The importance of the limit discussion was that it raised some issues on the potency, namely starting assumptions and SARs. **TUTB** had a reservation on this proposal as they preferred to apply the lower limit. The **NL** also expressed concern over this approach as it was possible to classify cobalt sulphate independently of the potency document, which after all was only a guidance document for the **Group** to use on a case-by-case basis. In asking the **Group** for their opinions on applying

the limits to both the sulphate and chloride, **BE** suggested applying the limit of 0.01 % to the sulphate **and no limit to the chloride**. **IRL** and **IT** supported this while **EL** preferred limits for both substances but could accept no limit for the chloride. **ES, DK, NL, A, FIN, S** and **N** preferred to apply the 0.01 % limit to both the chloride and sulphate compounds. As for the sulphate, the **UK, DE** and **FR** preferred not to apply limits until the potency issue had been discussed at length. In light of these comments, **it was agreed that cobalt chloride should not have a specific concentration limit applied**. Although **N** preferred to apply the lower limit to both substances, they could accept the **Group's** decision. They reminded the **Group** that this was an important issue for **N** and priority needed to be given it as soon as possible.

Conclusion:

The **Group** agreed to classify cobalt chloride with Carc. Cat. 2; R45: Xn; R22; R42/43; N; R50-53, symbols T; N; R-phrases: 45-22-42/43-50/53; S-phrases: 53-45-60-61 and Nota E. It was agreed not to apply a specific concentration limit before the potency issue had been discussed at greater length.

The proposal would be sent to DG XI for possible inclusion in a future TPC.

Extract from Summary Record of the Commission Working Group on Classification and Labelling - CMR, July 1998:

Cobalt (II) chloride (W004) (CAS No. 7646-79-9, EC No. 231-589-4).

Proposal: [Carc. Cat. 2; R45] : [Xn; R22] : [Xi; R37] : [R42/43] : N; R50-53.

[Specific concentration limit for carcinogenicity: 0.01%]

XI/393/93 - Add. 9	Ch. Arvius, EFTA - 14.3.94 classification proposals for W003, W004
XI/393/93 - Add. 24	EUROMETAUX, Cobalt and Carcinogenicity
XI/393/93 - Add. 29	UK HSE, Toxicity review 29 Cobalt and cobalt compounds
ECBI/26/95 - Add. 23	N, comments on classification of W003 & W004
ECBI/26/95 - Add. 24	DK, epidemiology studies of cobalt exposed women.
ECBI/26/95 - Add. 40	EUROMETAUX, comments on cobalt sulfate and chloride

Cobalt sulphate and cobalt chloride are problematic for **N** (EEA). Classification of both salts as N; R50-53 was agreed in April 1995. In October 1994, the **Group** discussed the classification proposal and agreed to postpone further discussion until results of the NTP study were available. In October 1997 the **Group** agreed to classify cobalt chloride with Carc. Cat. 2; R45: Xn; R22; R42/43; N; R50-53, symbols T; N; R-phrases: 45-22-42/43-50/53; S-phrases: 53-45-60-61 and Nota E. It was agreed not to apply a specific concentration limit before the potency issue had been discussed at greater length.

Following written comments from **Eurometaux**, the **Group** agreed to consider whether R45 or R49 was the most appropriate R-phrases for this substance. **B, DK, ES, FR, IRL, PT** and **UK** could all accept the proposal from **Eurometaux** for R49 together with S22. **NL** were strongly of the view that R45 was justified. **DE, IT, AT, FIN** and **SE** also favoured R45 to R49.

Given that there were no carcinogenicity data available specifically for this substance,

B, IRL and **UK** commented that it was inappropriate to use a potency estimation for setting a specific concentration limit in this case. **UK**, and **IRL** stated that they did not wish to set a specific limit for R49 for this substance. However, the similarity of this salt to cobalt sulphate was sufficient justification for **N, SE, FIN, PT, AT, NL, IT, ES, DK** and **DE** to conclude that this substance should be regarded as a highly potent carcinogen and that a specific limit of 0.01% for R49 should, equally, be applied to both cobalt salts.

Conclusion:

The **Group** agreed to classify cobalt chloride with Carc. Cat. 2; R49: Xn; R22; R42/43; N; R50-53, symbols T; N; R-phrases: 49-22-42/43-50/53; S-phrases: (2-)22-53-45-60-61. Nota E and Nota 1. A lower concentration limit of 0.01 % to cover concerns over carcinogenic potency was also agreed. The proposal would be sent to **DG XI** for possible inclusion in a future TPC.