

Status of a chelate on the chemical inventories

Scope:

This interpretation applies to:

EU (EINECS/ELINCS)	Australia (NICNAS AICS)
USA (TSCA)	Philippines (PICCS)
Canada (DSL/NDSL)	Switzerland
Japan (METI CSCL and MOL ISHL)	New Zealand
Korea (KECI)	

Responsibility:

The responsibility for the compliance of a product in a local market is always held by the persons placing the product on the market. This interpretation is shared in the spirit of openness and the hope that a common understanding of how to properly comply with the regulations can be reached. The author accepts no liability for any error in this information. Please note that the potential consequences of failure to comply with new chemical notification regulations can be severe, including immediate discontinuation of all product marketing and fines. In cases of doubt, companies are encouraged to consult the regulatory authorities in the countries where they plan to market a product.

Definition

Chelate complex: a coordination compound in which a central metal ion is attached by co-ordinate links to two or more non-metal atoms in the same molecule, called ligands.

Interpretation and Application

Complexes which form or may form in a mixture when a chelating agent is mixed with a metal salt, and which are not separated from the mixture, do not need to be notified as new chemical substances, as long as the metal salt and the chelating agent are both listed on the inventory of existing chemical substances.

This interpretation will be applied like the following example:

A product is made with the following raw materials:

Nickel chloride	CAS 7718-54-9
Gluconic acid	CAS 527-07-1

Then a metal chelate complex will occur in the aqueous solution:

Nickel gluconate	CAS 527-09-3
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Nickel chloride and gluconic acid are both listed on the inventory of existing chemicals. Therefore nickel gluconate is allowed also in a product for the relevant market. Please note, that if a company separates the nickel gluconate for sale or imports the nickel gluconate from a supplier to use in locally manufactured products, then the nickel gluconate must be notified as a new chemical (if it is not already in the listing).

Basis for Interpretation:

Europe:	"Substances which result from a chemical reaction that occurs when a chelating agent functions as intended should not be reported." (Manual of Decisions, 2.3.2.8)
USA	EPA is known to have approved the application of a section 720.30(h)(7) exemption for these mixtures. Please note that due to the complexity of TSCA issues and the potential consequences of failure to comply, a company which applies this interpretation is responsible to verify the applicability of the (h)(7) exemption on a case-by-case basis.
Canada:	Canada remains responsible to verify the applicability of exclusions or exemptions on a case-by-case basis.
Australia: Japan: Korea:	Confirmation from an industry leader is on file demonstrating that the authorities support the interpretation that the metal chelate compound is a mixture. If both the starting components are listed, the metal chelate compound is legal on the respective market. (Chelate guideline Japan Korea Australia.pdf)
Others:	Analogy to the above interpretations is used, due to lack of specific guidance published by the authorities.