

Meeting 28th May 2008

SPECIAL PREPARATIONS WORKSHOP

Preparations and Special Preparations

- **What's the difference?**
- **Implications for downstream legislation**

Preparations and Special Preparations

REACH defines a preparation as follows:-

"Preparation means a mixture or solution composed of two or more substances"

This definition assumes that there is no reaction between the constituent substances and that they retain their intrinsic properties in the mixture

For example, a mixture of common salt (NaCl) and sand meets this definition

Preparations and Special Preparations

In other mixtures, as a result of their inclusion within a chemical matrix, the properties of one or more constituent substances cannot be directly applied to the properties of the preparation

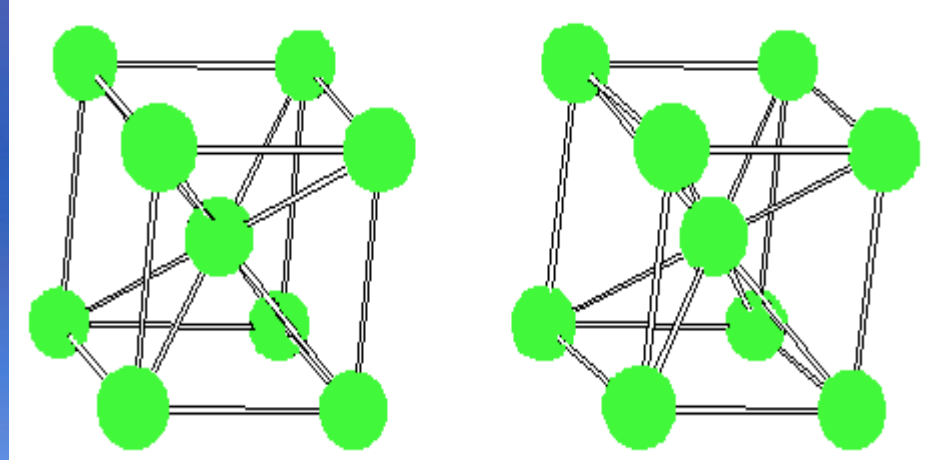
Such mixtures have become known as “Special Preparations”

Metallic alloys and rubber compounds are familiar examples of special preparations

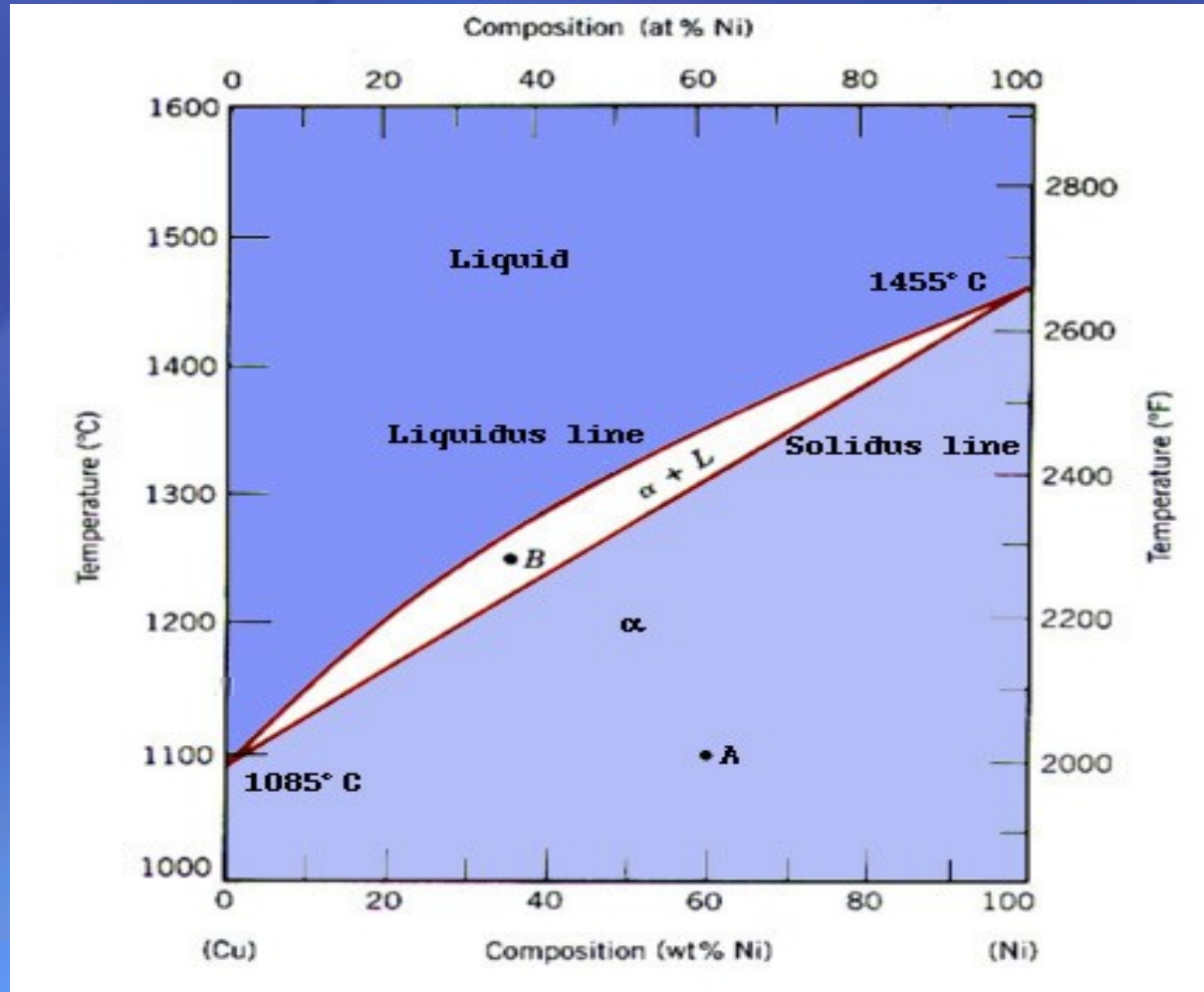
The “chemical matrix” is a key feature of special preparations

Preparations and Special Preparations

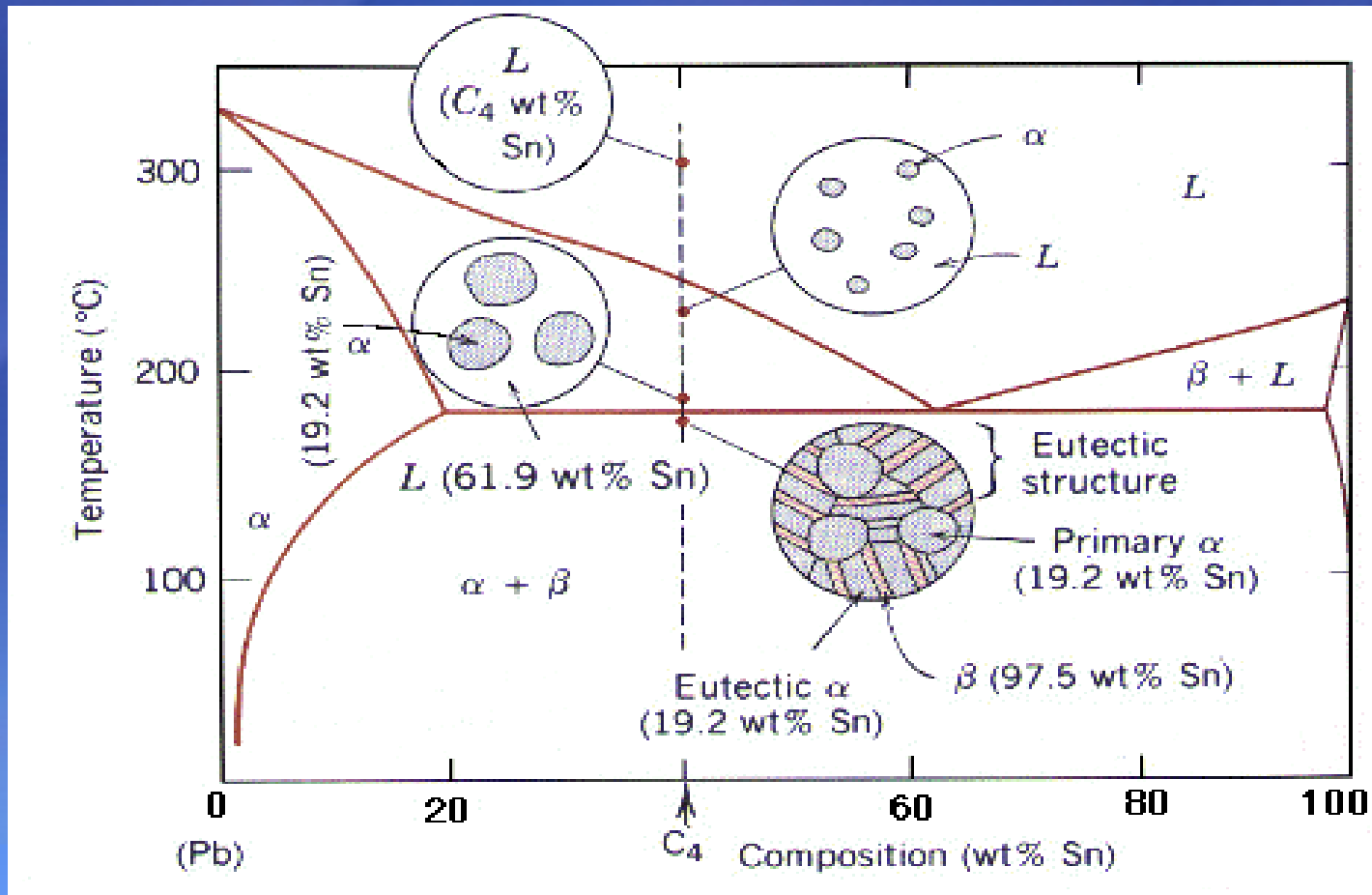
The matrix in metals and alloys is formed metaalic bonds, which crystal lattices with long range order



Preparations and Special Preparations

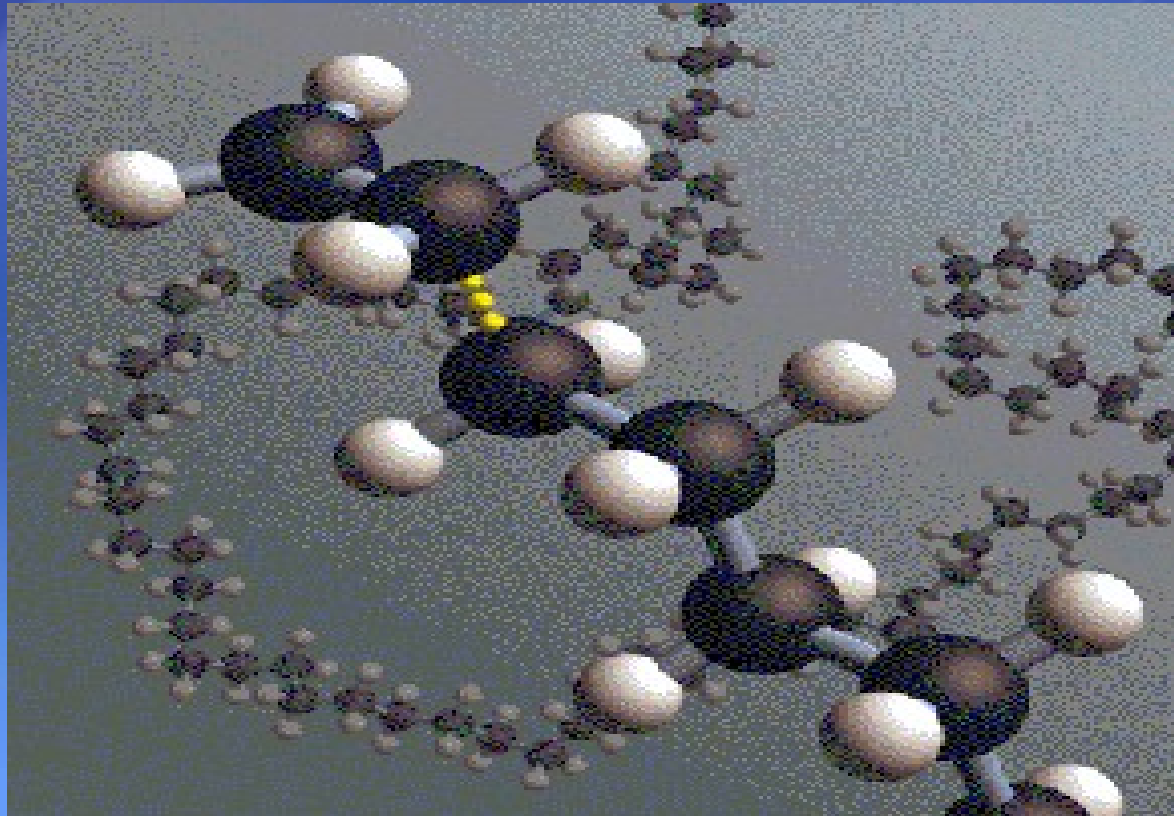


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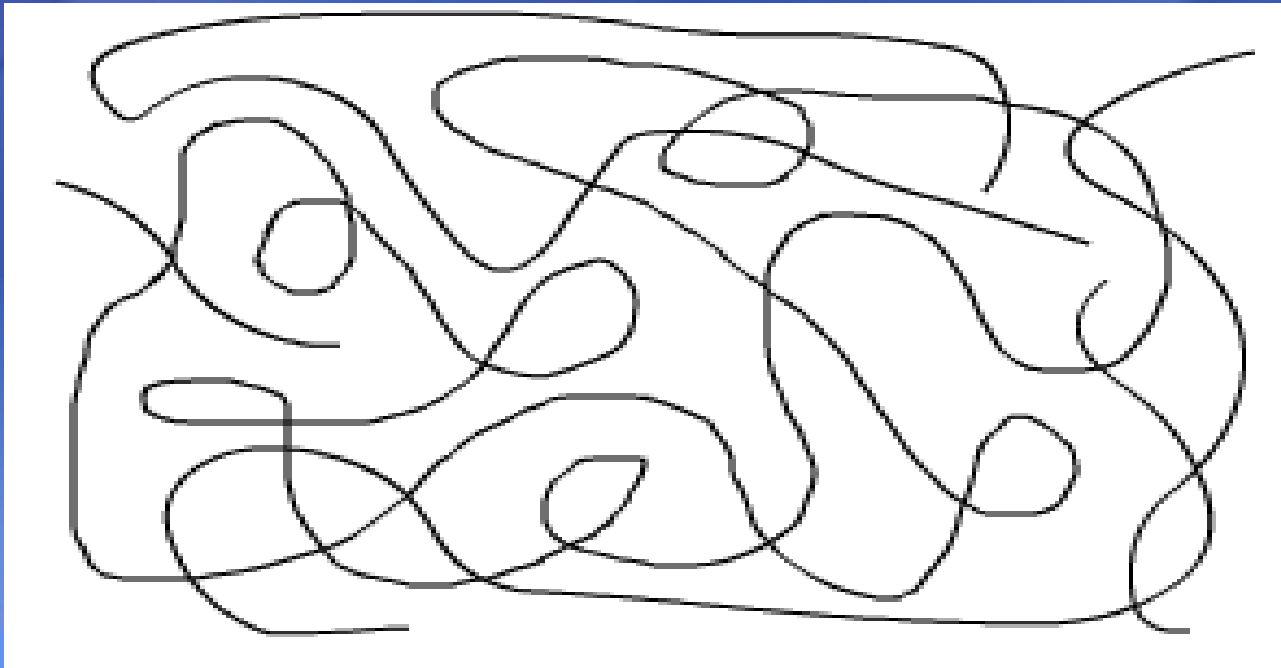
Preparations and Special Preparations

The matrix in polymeric materials is formed by long chain molecules with covalent and ionic bonds formed between the atoms



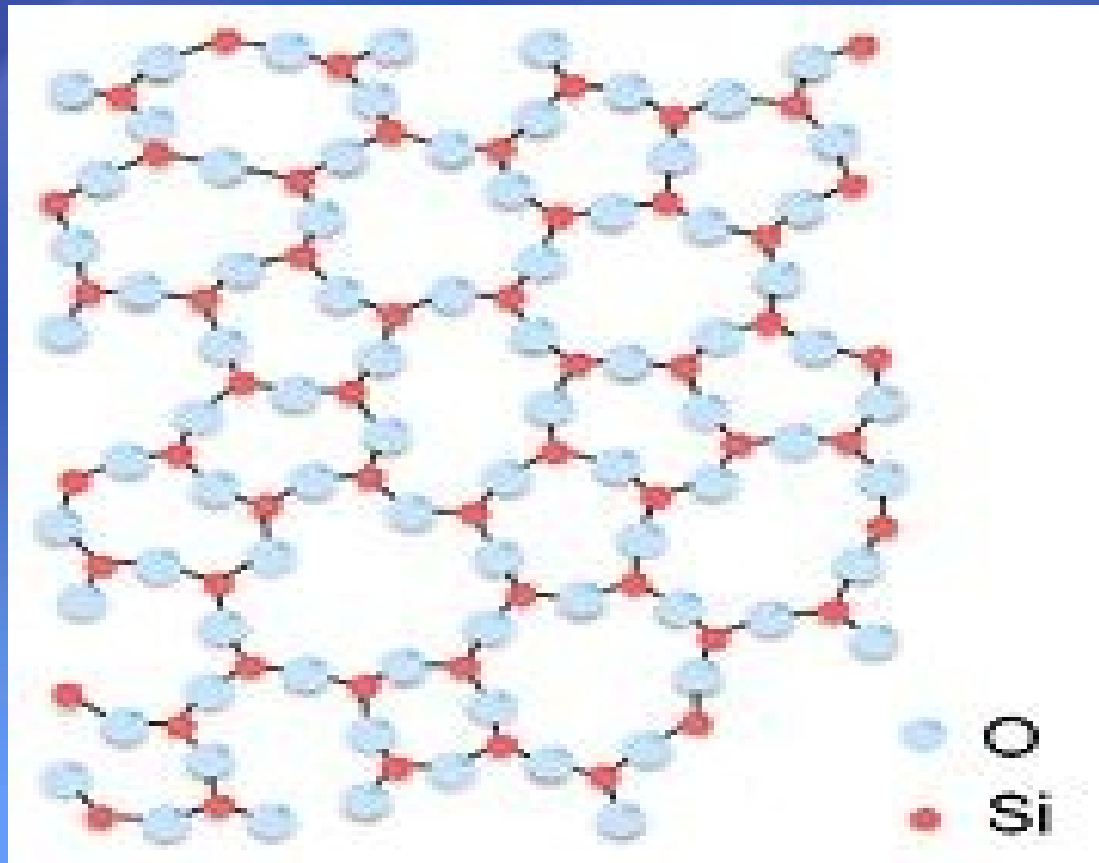
Preparations and Special Preparations

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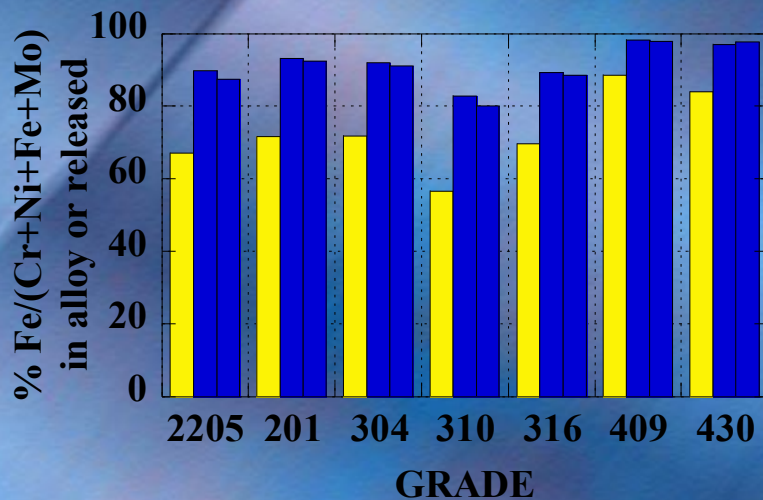
Preparations and Special Preparations

The amorphous structure of glassy Silica (SiO_2) has no long range order is present. However, there is local ordering with respect to the tetrahedral arrangement of Oxygen (O) atoms around the Silicon (Si) atoms

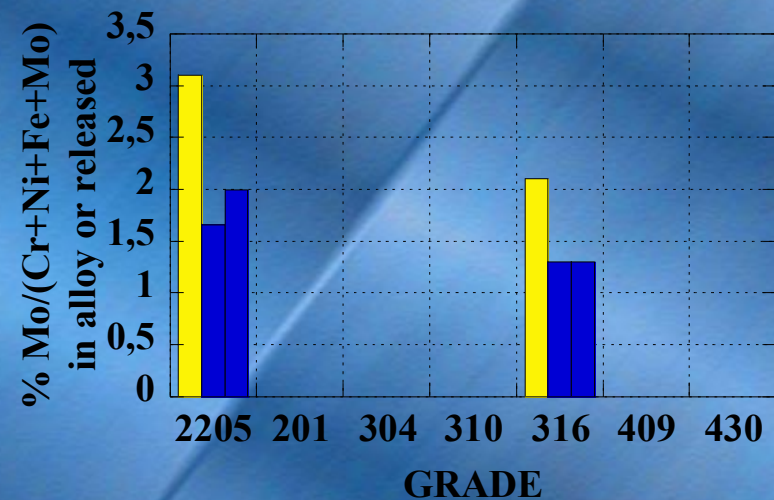


Mass balance calculations based on release rates in Cytosol and bulk alloy composition. (abraded surfaces)

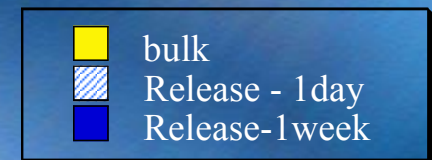
iron



molybdenum



Fe is predominantly released and the release of Mo is considerably lower than corresponding bulk alloy composition, for all grades investigated.



Special Preparations

REACH Annex I, paragraph 0.11 states

“When assessing the risk of the use of one or more substances incorporated into a special preparation (for instance alloys), the way the constituent substances are bonded in the chemical matrix shall be taken into account.”

Hence, the following working definition is proposed:-

“Special preparation means a mixture in which the intrinsic properties of one or more constituent substances, as a result of their inclusion within the chemical matrix, cannot be directly applied to the properties of the mixture.”

Special Preparations

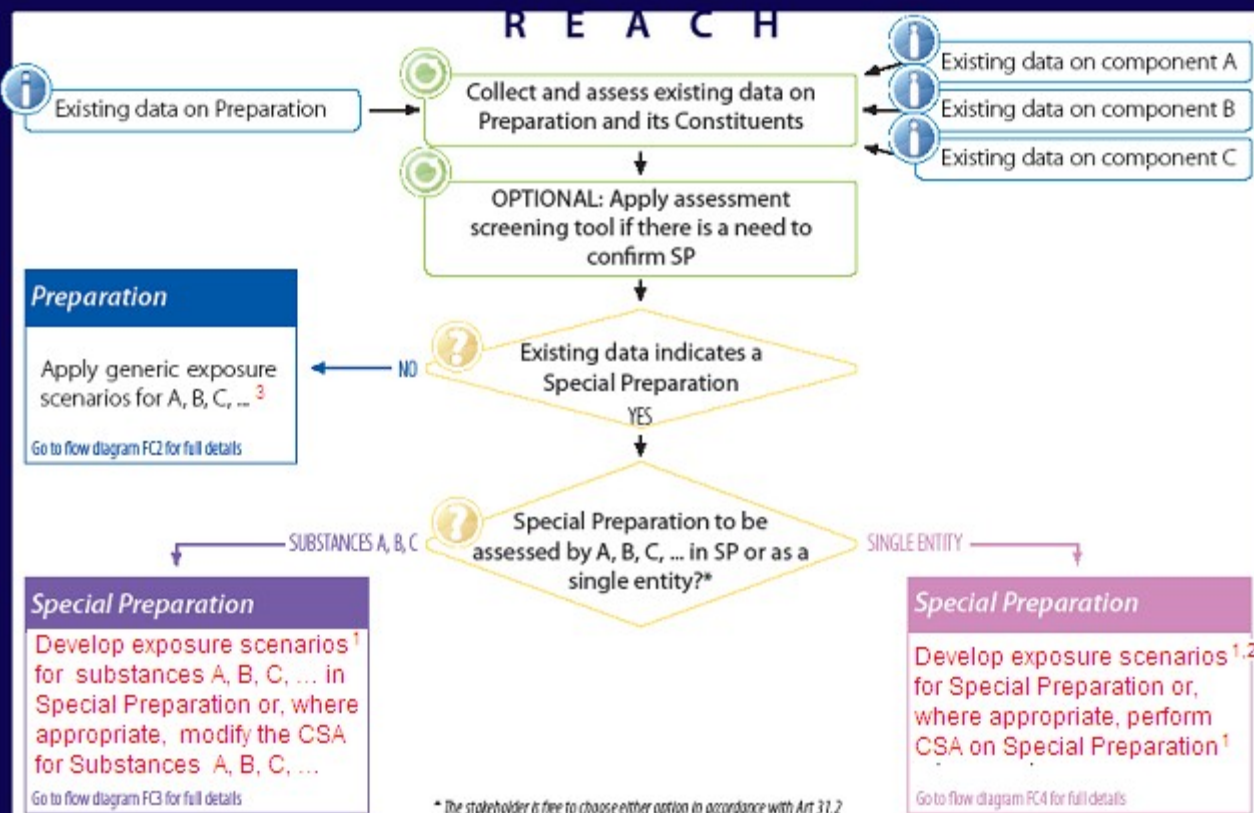
Recital (31) states

“The Commission, in close cooperation with industry, Member States and other relevant stakeholders, should develop guidance to fulfil the requirements under this Regulation related to preparations (in particular with regard to safety data sheets incorporating exposure scenarios) including assessment of substances incorporated into special preparations — such as metals incorporated in alloys. In doing so, the Commission should take full account of the work that will have been carried out within the framework of the RIPs and should include the necessary guidance on this matter in the overall REACH guidance package. This guidance should be available before the application of this Regulation.”

In response, industry has developed the following flow diagrams, supported by a written text, as guidance on the assessment of special preparations

Special Preparations

Flow diagram FC1: Overview of the assessment of Preparations and Special Preparations



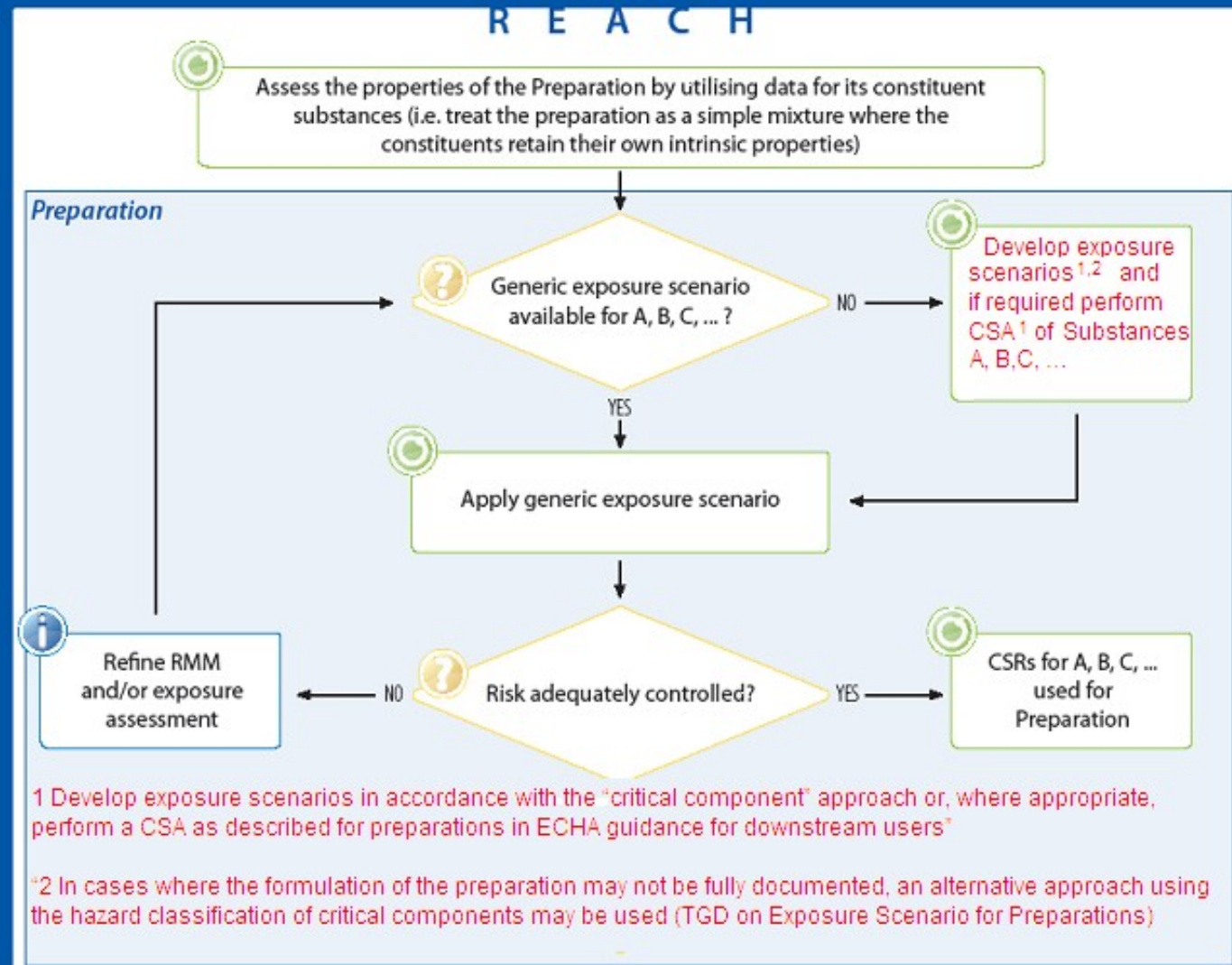
1: Develop exposure scenarios in accordance with the "critical component" approach or, where appropriate, perform a CSA as described for preparations in ECHA guidance for downstream users

2: Apply or, where appropriate, develop generic exposure scenarios to cover a range of preparations

3: Refer on TGD on Exposure Scenario for Preparations

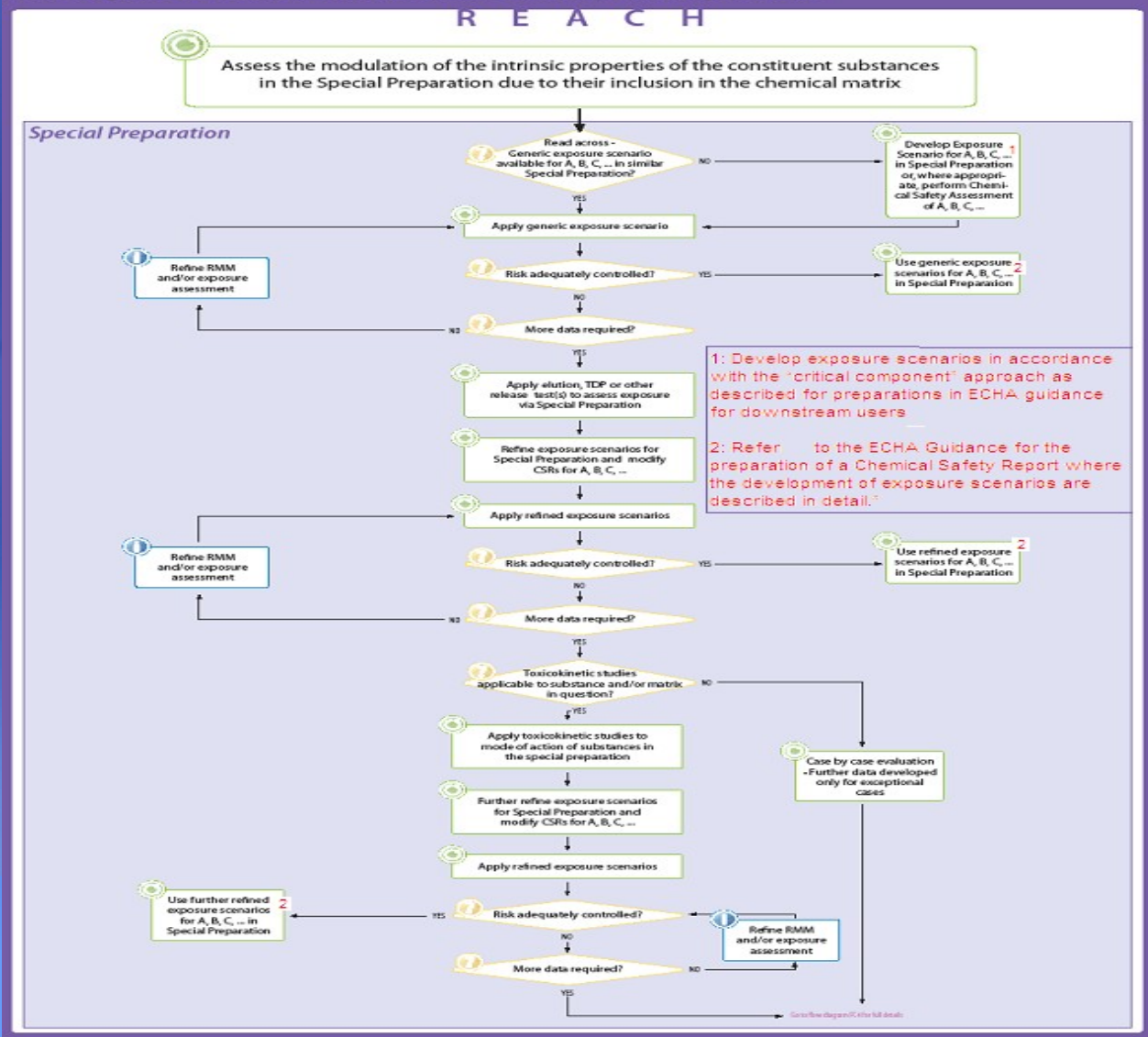
Special Preparations

Flow diagram FC2: Guidance for the Assessment of Preparations



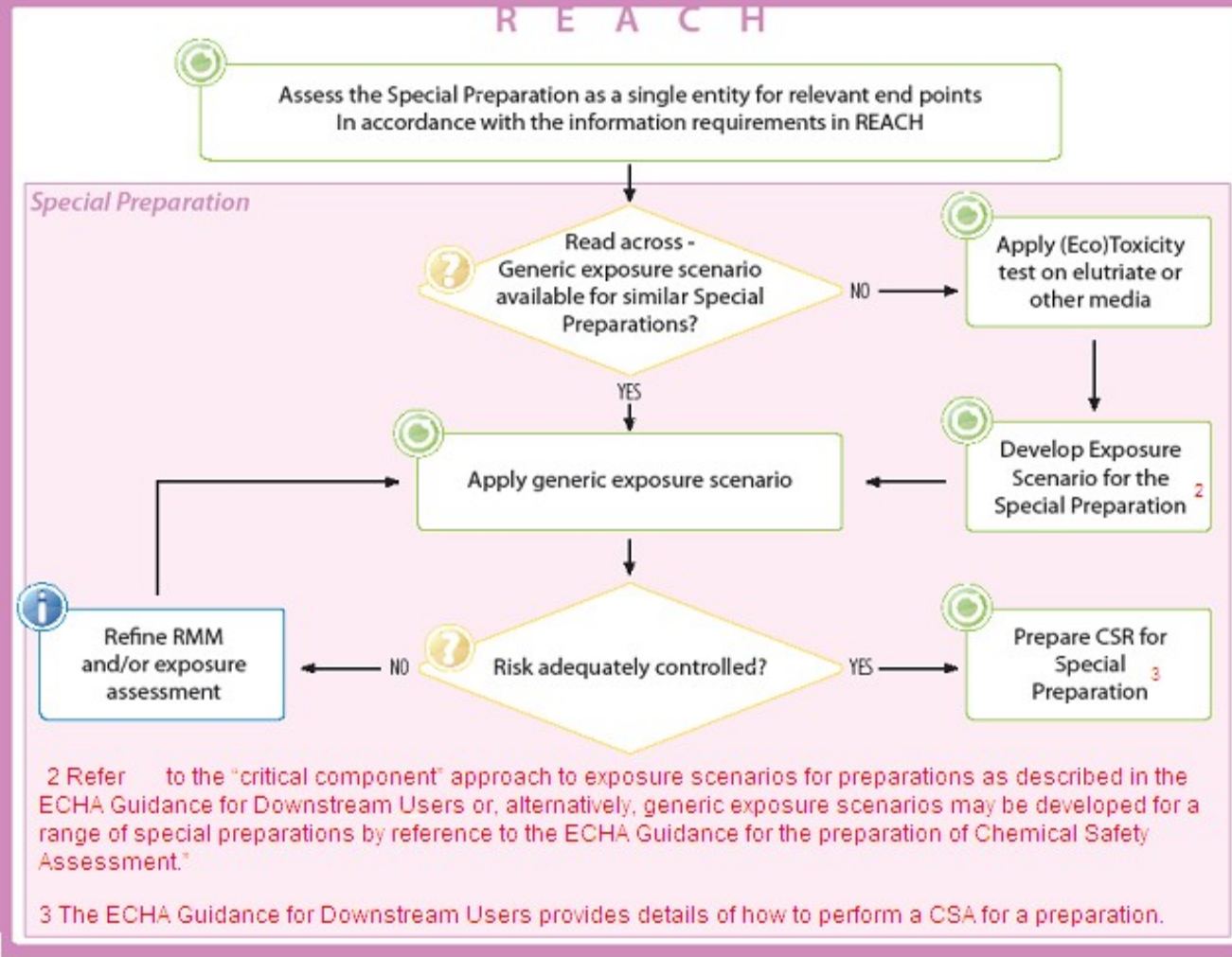
Special Preparations

Flow diagram FC3: Guidance for the Assessment of Special Preparations



Special Preparations

Flow diagram FC4: Guidance for the Assessment of Special Preparations as a single entity



Special Preparations

Implications for downstream legislation

EU chemical-related downstream legislation is generally based on the hazard classification of substances and substances in preparations rather risk

This is a disadvantage for special preparations, where the potential hazard may not be expressed by a special preparation

Example 1: Nickel metal is a known dermal sensitiser and, therefore, the Marketing and Use Directive (Restriction under REACH) prevents the use of any nickel-containing articles in close and prolonged contact with the skin. However, when tested in accordance with EN 1811 (the sweat test) nickel containing stainless steels release less than 0.5 µg/cm²/week of nickel and they are not dermal sensitisers

Special Preparations

Implications for downstream legislation

Example 2: Crystal glass contains 24% Pb (lead) and, therefore, there are concerns about its use for food and beverage applications

Tests using common beverages consumed from crystal glass demonstrated that Pb release at level close to the limit of detection (i.e. $1 \mu\text{g}/\text{cm}^2/\text{week}$) – a very small contribution to the total tolerable daily intake for lead