DiaSorin The Diagnostic Specialist

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Comments presented by Diasorin on the inclusion of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated in the Candidate List under Title VII of REACH Regulation

This position paper is presented on behalf of DiaSorin S.p.A. (hereinafter “DiaSorin”), as a downstream user of the substance 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated.

Recently, the substance at issue has been included in the Candidate List for eventual inclusion in Annex XIV, according to Title VII of Regulation (EC) 1907/2006 (hereinafter "REACH"). However, DiaSorin submits that there is no basis for such a qualification or, at least, that an exemption from the authorization must be granted for DiaSorin's use of the substance for in vitro diagnostics purposes, as further discussed below.

Summary

DiaSorin uses 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated as a surfactant in the manufacturing of reagent kits for in vitro diagnostics regulated under EC Directive 98/79/EC. This substance has recently been included in the Candidate List for authorisation, under Title VII of Regulation (EC) 1907/2006. However, the use of the substance is already adequately covered by other EU legislation on in vitro diagnostics. Furthermore, substance at hand is used under strictly controlled conditions, in compliance with the EU legislation in force applicable to in vitro diagnostic medical devices. Moreover, exposure to the substance is very limited and in any event occurs in a controlled environment. . Therefore, there are solid legal grounds for allowing the continued use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated, as a surfactant in the manufacturing of reagent kits for in vitro diagnostics, without any authorization requirements.

1. Background

DiaSorin is a company developing, producing and marketing reagent kits for in vitro diagnostics. 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated, is used as a surfactant in the manufacturing of those reagent kits to disaggregate proteins and remains in the finished product in a quantity equal to or less than 1%.

The product array manufactured by DiaSorin is diversified by pathology/application sector and encompasses assays for the determination of serological parameters in:

- Endocrinology
- Oncology

- Bone & mineral metabolism
- Infectious diseases
- Autoimmunity.

The production and marketing of the DiaSorin's reagent kits for in vitro diagnostics are authorized by the Local Ministry of Health when appropriate and required. On account of its unique characteristics, 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated, is hardly replaceable with other similar substances, without adversely affecting DiaSorin's production process.

DiaSorin's end customers are clinical laboratories, hospitals and specialized health care facilities as well as small and medium sized independent clinical laboratories. There is no consumer exposure involved.

The substances covered by the entry 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated, have been recently identified as substances meeting the criteria of Article 57(f) REACH because of their potential endocrine disrupting properties (through their degradation) and possible serious effects to the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH. They were therefore included in the Candidate List for authorisation on 19 December 2012, following ECHA's decision ED/169/2012.

The inclusion in Annex XIV would mean for DiaSorin that it will be prevented from using 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated, unless the use of that substance is authorized or exempted from the authorization requirement.

However, by this position document, DiaSorin submits that its use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated is to be exempted from the authorization requirement as in the use of the substance at issue the risk is properly controlled according to existing specific EU legislation.

2. Exemption of the use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated by DiaSorin, according to art. 58.2 REACH (Community legislation adequately controlling the risks – proportionality)

The use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated made by DiaSorin falls within the scope of art. 58.2 as exempted use / category, since the risk stemming from those activities is already regulated by specific EU legislation imposing minimum requirements relating to the protection of human health and the environment.

Indeed, DiaSorin is obliged, under specific EU legislation regarding in vitro diagnostic medical devices, to ensure a high level of protection of human health and safety.

The flow production of a DiaSorin's kit includes the processing from raw materials to obtain biological and biochemical semi-finished and intermediate good and, afterwards, reagent kits. It is to be noted that 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated, is used under constantly strictly controlled conditions, in terms of both process and functionality.

Directive 98/79/EC lays down the requirements that are necessary to ensure, under the best safety conditions, free movement of the in vitro diagnostic medical devices.

To comply with the above-mentioned EU legislation, 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated, is rigorously contained by technical means during its whole lifecycle and procedural and control technologies that minimise emission and any resulting exposure have been implemented. In addition, other safeguards exist, notably:

1) only properly trained and authorised personnel can handle the substance;
2) in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;
3) in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures;
4) substance-handling procedures are well documented via a proper technical document management systems and strictly supervised by the site operator.

Moreover, further to the processing described above, the risk to human health and the environment is fully neutralized, since the substance remains in extremely small quantities (equal to or less than 1%) in the finished product.

DiaSorin has recently carried out specific dispersal measurements in its premises to assess the exposure of its personnel to possible emissions. These tests have shown that the 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated, is not present in the air sampled in the working areas (or under the limit of detection) and therefore cannot produce any dangerous emission in the laboratories of production or of the professional final end users.

Therefore, it would be contrary to the principle of proportionality not to grant an exemption from Annex XIV for the use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated, in the manufacture of in vitro diagnostic reagent kits.

Based on the foregoing, we respectfully submit a request for exemptions on the basis of Article 58.2 of REACH in relation to DiaSorin's use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated, as a surfactant in the manufacturing of reagent kits for in vitro diagnostics, as the risks are already adequately controlled by other existing EU legislation on in vitro diagnostics imposing minimum requirements relating to the protection of human health and the environment. Moreover, the quantities involved in the use of the substance for reagents kit is so small that, in any event, there is no risk for man or the environment.

Saluggia, 20.9.2013

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