SD BIOSENSOR

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Subject: Exemption from the Authorization requirement of the REACH Regulation.

The purpose of this document is to describe and justify the exemption of the product from the authorization requirement of the REACH Regulation, as defined under REACH Article 56 (3) and Q&A ID: 1442[1] as "scientific research and development (SRD) exemption, where the exemption for In Vitro Diagnostics applies."

This products are manufactured by SD Biosensor, Inc., based in Korea, and they contains Octylphenol, ethoxylated; "Triton™ X-100" (=OPE) in a concentration of 1.5% w/w of the kit component and its finished products. SD Biosensor will present this document to the authorities upon request.

Description

The substance below is included in Annex XIV of the REACH Regulation:

- CAS-No.: 9002-93-1; Octylphenol, ethoxylated; "Triton™ X-100" (=OPE)

Table 1a lists the finished good (kit) distributed by SD Biosensor for in vitro diagnostic use (CE-IVD). This product falls under the SRD exemption according to Art. 56(3) of the REACH Regulation and Q&A ID: 1442, "IVD exemption"

Table 1a: Finished CE-IVD goods, containing OPEs, where IVD exemption, Q&A ID: 1442 applies

REF No.	Product Name	Substance	%
Q-NCOV-01G	STANDARD™ Q COVID-19 Ag Test	OPE	1.5%
Q-NCOV-03G	STANDARD™ Q COVID-19 Ag Home Test	OPE	1.5%
Q-NCOV-04G	STANDARD™ Q COVID-19 Ag Nasal Test	OPE	1.5%

Table 1b lists the respective kit component of the finished products in Table 1a, which is sold by SD Biosensor for In Vitro Diagnostic (CE-IVD) use. These products fall under the SRD exemption according to Art. 56(3) of the REACH Regulation and Q&A ID: 1442 for in vitro diagnostics.

Table 1b: OPE containing CE-IVD kit component, where IVD exemption and Q&A ID: 1442 applies

REF No.	Product Name	Substance	%
n/a	Extraction Buffer Tube	OPE	1.5%

[1] : Q&As - ECHA (europa.eu)

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Justification

The products listed in Tables 1a and 1b contain OPE in the final formulation. This use of OPE falls under Article 56 (3) of the REACH Regulation and fulfills the conditions defined in "Questions and Answers" provided by the European Chemicals Agency in Q&A ID: 1442.
According to Q&A 1442, the use of Annex XIV substance (here: OPE) on its own is considered as in vitro diagnostics use and is there exempted from authorization requirements if this activity is carried out under controlled conditions and in a volume not exceeding one ton per year and legal entity.

Volume condition

As defined in the answer Q&A 1442, the total annual quantity for all products listed in Tables 1a and 1b at the customer site is less than 1 ton/year. It is the customer's obligation and responsibility to fulfil this condition on annual volumes.

Conclusion

The products listed in Tables 1a and 1b fulfil the criteria for exemption from the authorization requirement under the REACH regulation as described under Article 56 (3) and Q&A ID: 1442. The use of Octylphenol ethoxylates is exempted from authorization if this activity is carried out under controlled conditions and in a volume not exceeding one ton per year and per legal entity.
SD Biosensor implements sufficient measures to inform about the presence of OPE/NPE and the prerequisites usage (controlled condition and the 1t/a condition).
In parallel, a substitution project to ensure the phase out of OPE in the component as well as finished goods listed in table 1a and b is rigorously pursued to be implemented in the due course.

Sincerely,
Geun-Kuk Song
QMR
SD BIOSENSOR, Inc.