

Document Released August 1st 2010

Statement on Regulation (EC) No 1907/2006 of the European Parliament and the Council, released 18th of December 2006, concerning the Registration, Evaluation and Authorization of Chemicals (REACH) on 30 December 2006 published in the EU Official Journal 396/1

To Whom it May Concern:

On 1st of June 2007 Regulation (EC) No 1907/2006 concerning Registration, Evaluation, Authorization and Restriction of Chemicals¹ ("REACH" for short) came into force.

REACH contains the following regulations:

- 1. From the 1st of June 2008 on, manufacturers of substances, and importers of substances as such or of substances in preparations (mixtures) into the European Community (EC) and the European Economic Area (EEA), must register these substances with the European Chemicals Agency, if the substances in question are manufactured or imported in quantities of at least 1 t/a and if they are not substances that are exempted from compulsory registration. So-called "phase-in substances" these are, for example, substances that are shown on the existing substances list EINECS can be preregistered between the 1st of June 2008 and the 1st of December 2008. Preregistered substances do not have to be registered until later, depending on the quantity manufactured/imported.
- 2. Suppliers of substances and preparations must provide the recipient with either a safety data sheet (Article 31) or safety information (Article 32). In certain cases, the safety data sheet will be supplemented by an annex ("extended safety data sheet") showing the relevant exposure scenarios.
- 3. Manufacturers and importers of articles that contain more than 0.1 mass percent per article of a substance on the "candidate list" shall provide the professional recipient and, on request, a consumer of the article, with sufficient information to allow safe use of the article, including, as a minimum, the name of that substance. If all these articles contain more than 1 t/a, a notification to the European Chemicals Agency (EChA) is necessary, however, not before the 1st of June 2011.
- 4. From the 1st of June 2008, users of chemicals (substances and preparations/mixtures) so-called "downstream users" will have to comply with other obligations, but in some cases only after they have received an extended safety data sheet. Downstream users can provide appropriate information so as to assist the manufacturers of substances and importers of substances and preparations in registering them.

REGULATION (EC) NO. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

The products BioZone Scientific is manufacturing for you are exclusively articles (not chemicals) which are not intended to release any substance under normal and reasonably foreseeable conditions of use. Consequently, the obligations in No. 1 and 2 above are not relevant here.

Regarding Article 33 of REACH (see 3, reporting requirement on SvHC-substances), we inform you that the "Candidate List of Substances of Very High Concern for authorization" as required under Article 59 (1, 10) of Regulation (EC) No 1907/2006 ("REACH") is published on the website of the European Chemicals Agency (EChA) at http://echa.europa.eu/.

See also http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp.

According to our information from our supply chain, the components of our products and therefore our products themselves contain no substances² above 0.1% by mass, which were included in the "candidate list".

Best regards,

Adam Anthony

Chief Operating Officer

BioZone Scientific International, Inc. 7751 Kingspointe Parkway, Suite 124

Orlando, FL 32819 United States of America

Phone: +1 407-876-2000 Fax: +1 407-876-7630

Email: adam.anthony@biozonscientific.com