

### **SCREENING REPORT**

# TO ASSESS WHETHER THE USE OF SIX SODIUM PERBORATES IN ARTICLES SHOULD BE RESTRICTED IN ACCORDANCE WITH REACH ARTICLE 69(2)

Annex XIV entry	Substance name	EC	CAS	Latest application date	Sunset date	Intrinsic property
48	Sodium perborate	239-172-9	15120-21-5	27/11/2021	27/05/2023	Toxic for reproduction (Article 57c)
48	Perboric acid, sodium salt	234-390-0	11138-47-9	27/11/2021	27/05/2023	Toxic for reproduction (Article 57c)
48	Perboric acid (H3BO2(O2)), monosodium salt, trihydrate	603-902-8	13517-20-9	27/11/2021	27/05/2023	Toxic for reproduction (Article 57c)
48	Borate(2-), tetrahydroxybis[μ- (peroxy- κ01:κ02)]di-, sodium, hydrate (1:2:6)	-	125022-34-6	27/11/2021	27/05/2023	Toxic for reproduction (Article 57c)
48	Borate(2-), tetrahydroxybis[μ- (peroxy- κ01:κ02)]di-, sodium (1:2)	-	90568-23-3	27/11/2021	27/05/2023	Toxic for reproduction (Article 57c)
49	Sodium Peroxometaborate	231-556-4	7632-04-4	27/11/2021	27/05/2023	Toxic for reproduction (Article 57c)

Source: https://echa.europa.eu/authorisation-list

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**VERSION:** 1 - Final **DATE:** 2 June 2023

#### 1. Conclusions

Following an assessment of the available evidence, ECHA considers that there is no use of the group of substances covered by entries 48 and 49 of REACH Annex XIV in articles (domestic or imported) which may pose a risk to human health that is not adequately controlled.

The six sodium perborates covered by entries 48 and 49 of REACH Annex XIV are toxic for reproduction (Article 57c). However, there is no information that indicates that the use or presence of these substances in articles would lead to human exposure.

Therefore, under REACH Article 69(2), ECHA's view is that at present there is no need to prepare an Annex XV dossier for restriction.

The call for evidence on the six sodium perborates took place from 26 October to 7 December 2022. The information provided by German Competent Authority was considered and is reflected in the final version of this report.

## 2. Summary of findings

#### 2.1. Identified uses

The combined evidence from the EU regulatory documents, SCIP database, and online searches indicates that the six sodium perborates covered by this report may have uses in the manufacturing of articles, the most likely being in the manufacturing of electronic components and/or their production process. Nevertheless, given the technical function of the six sodium perborates (oxidising, cleaning, and bleaching agent), and given their reactive nature, it is expected that the six sodium perborates are unlikely to be present in the articles placed on the market. No information was submitted during the call for evidence to confirm or contradict this assumption.

Only one of the six sodium perborates, namely perboric acid sodium salt (EC 234-390-0), has been registered in the EU. In 2022, two registrations were active (REACH Annex X, >1 000 tonnes per year). Information from 2013<sup>1</sup> indicates that the EU production volume was estimated to be <40 000 t/y. This information was not contradicted during the call for evidence.

The 2010 REACH registrations do not indicate any article uses. The previous regulatory documents<sup>2</sup> indicate that perboric acid sodium salt has been used as an **oxidising and bleaching agent** in chemical preparations such as laundry detergents, automatic dishwashing detergents, stain removers and cosmetics (e.g. denture cleansers and hair dyes).

As the sunset date for these six sodium borates has passed, and no applications for authorisation were submitted to ECHA for any of them, only a limited number of uses are still allowed in the EEA<sup>3</sup>. These are uses that are exempted from authorisation<sup>4</sup>.

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<sup>&</sup>lt;sup>1</sup> <u>Draft background document for sodium perborate, perboric acid, sodium salt</u> – ECHA's Seventh Recommendation for the inclusion of substances in Annex XIV, 2015

<sup>&</sup>lt;sup>2</sup> Annex XV report for the identification of perboric acid, sodium salt as a Substance of Very High Concern for its CMR properties

<sup>&</sup>lt;sup>3</sup> For further information on the uses of the substance and regulatory actions, please consult <u>ECHA's website</u>

<sup>&</sup>lt;sup>4</sup> Generic exemptions from the Authorisation requirement

Available online information indicates that perboric acid sodium salt is still manufactured in commercial volumes in other regions of the world and the other five substances have a limited number or no suppliers. The manufacturers are mainly in China and the USA<sup>5,6</sup>.

There is no information available, neither in the registration dossiers nor in the Annex XV dossier for SVHC identification, on the potential function and use of these six substances in articles. In addition, ECHA has not received any substances in articles notifications in accordance with Article 7(2) of REACH<sup>7</sup>.

These substances have been notified to the SCIP database<sup>8</sup> under the Waste Framework Directive<sup>9</sup> and information retrieved from external databases searches as follows:

• A small number of notifications reporting the presence of three of the six sodium perborates in articles were submitted to the SCIP database for the following categories: electrical machinery and equipment and parts thereof, including transmission apparatus, radios, monitors and projectors, components of electronic appliances such as diodes, disk varistors and engrave plates; parts and accessories of the motor vehicles; parts and accessories for optical, cinematographic, measuring etc. appliances, instruments or apparatus.

The substances notified to the SCIP database are indicated to be present in the following materials: copolymers of acrylonitrile-butadiene-styrene; alkyd resins plastic and polymers, or polyamide or nylon; and polymers and copolymers of olefins or in precious metal and their alloys.

The SCIP database does not contain information on the function of the sodium perborates in the above-mentioned articles/materials or complex articles.

- As SCIP notifications indicate that the substances might be present in polymeric materials, a list of over 400 of the most commonly used functional additives and pigments in plastics that ECHA has developed jointly with industry – PLASI Initiative<sup>10</sup> - was reviewed. However, none of the substances covered by this report are included in the PLASI-list, indicating that the substances are most probably not used as additives in the production of polymers, or articles made of polymers.
- Searches in various external databases<sup>11</sup> indicate the use of the sodium perborates in sectors that manufacture articles with limited details about the use.
- Old data in the SPIN<sup>12</sup> database indicate that three of the sodium perborates (perboric acid sodium salt, sodium perborate tetra hydrate, and sodium peroxometaborate) have been reported to Nordic countries, until 2007 or earlier, as being used as cleaning

<sup>&</sup>lt;sup>5</sup> For example <u>Chemical Register</u> lists 13 suppliers

<sup>&</sup>lt;sup>7</sup> Producers and importers have to notify ECHA the substances listed on the Candidate list which are present in their articles, if both the following conditions are met: i) the substance is present in their relevant articles above a concentration of 0.1% w/w; ii) the substance is present in these relevant articles in quantities totalling over 1 tonne per year. Companies have to notify no later than six months after the inclusion of the substance in the Candidate List. For further details

<sup>&</sup>lt;sup>8</sup> In accordance with the Waste Framework Directive (WFD), companies supplying articles containing substances on the Candidate List in a concentration above 0.1% w/w on the EU market have to submit information on these articles to ECHA, from 5 January 2021. The information provided is included in the SCIP database, i.e., Substances of Concern In articles as such or in complex objects (Products).

<sup>&</sup>lt;sup>9</sup> <u>Directive 2008/98/EC</u> of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives

<sup>&</sup>lt;sup>10</sup> https://echa.europa.eu/mapping-exercise-plastic-additives-initiative

<sup>&</sup>lt;sup>11</sup> Danish Chemicals in Consumer Products Database, Consumer Product Information Database (USA & Canada); OECD Global Products Recall; Children's Safe Product Act Reported Data; Crest search engine; ChemSec Sinlist; Comparative Toxicogenomics Database; International Agency of Research on Cancer (IARC) monographs; California Department of Pesticide Regulation; Pesticide info.org

<sup>&</sup>lt;sup>12</sup> Substances in Preparations in Nordic Countries

**agents** in the manufacture of textile (and fur) of food products and beverages, maintenance and repair of motor vehicles and motorcycles, and in the repair of personal and household goods. More recent SPIN data does not indicate article related uses.

- The US EPA's Food Contact Database <sup>13</sup> lists perboric acid sodium salt as a food contact chemical unfortunately the database does not provide more detailed information about the uses, for example if the perborates are used merely for cleaning.
- The use of inorganic peroxo compounds in the electronics industry for etching printed circuits, due to their oxidising properties, is reported in literature<sup>14</sup>.

The information collected tends to confirm that the six sodium perborates may be used in the production of articles. Nevertheless, due to the reactive nature of the substances (see section 2.2), it is uncertain how much, if any, of the substances would be left in an article, if used during article production. For example, in an aluminium surface treatment application<sup>15</sup>, the function of sodium peroxometaborate is to form a hydrated oxide coating on the treated article.

#### 2.2. Hazards, emissions/releases/exposure and risk

#### Information on hazards

The six sodium perborates are included in REACH Annex XIV based on their toxic for reproduction, category 1B properties (Article 57c).

The six sodium perborates are reactive oxidants and liberate hydrogen peroxide and sodium borate/boric acid in aqueous solution, which is considered to be the cause of the induction of the adverse effects on development and fertility.

Other endpoints are not relevant for this report.

Information on emissions/release/exposure

Based on SCIP database submissions and limited evidence available on databases, three of the six sodium perborates have been indicated to be present in a small number of electronic components. However, given their reactive nature and technical function as oxidising, cleaning and bleaching agent, it is expected that they are unlikely to be present in articles.

This assumption and conclusion were not contradicted during the call for evidence.

#### Characterisation of risk

Based on the information presented above, it is expected that there is no risk because the presence of the six sodium perborates covered by entries 48 and 49 of Annex XIV in articles is unlikely.

This assumption was not contradicted during the call for evidence.

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<sup>&</sup>lt;sup>13</sup> Food Contact Chemicals Database (FCCdb)

<sup>&</sup>lt;sup>14</sup> Ullmann's Encyclopaedia of Industrial Chemistry

<sup>&</sup>lt;sup>15</sup> Patent information on <u>SciFinder</u><sup>N</sup>

#### Background and scope of Article 69(2) screening

This screening report is prepared according to Article 69(2) of REACH Regulation (EC) No. 1907/2006. The article requires that ECHA, after the sunset date has passed for a substance included on the Authorisation List (Annex XIV), considers if risks from the use of the substance in articles are adequately controlled and, if this is not the case, prepares an Annex XV restriction dossier.

Thus, this screening report is targeted at the potential release or exposure to the Annex XIV substance(s) from an article throughout its lifecycle (including the waste stage) and whether such use(s) should be restricted. The report is focused on the human health and/or environmental hazards due to which the substance is placed on the Annex XIV. Other hazards are not required to be taken into account for the purpose of the screening. Similarly, in the event ECHA proposes that an Annex XV dossier for restrictions is prepared, the scope of the work will be restricted to the risks arising from the Annex XIV intrinsic properties only unless the scope is expanded on request by the European Commission to include other endpoints. It is to be noted that REACH restrictions do not apply in certain cases. These include manufacture and placing on the market or use of a substance in scientific research and development, risks to human health of the use of the substance in cosmetic products, and when a substance is used as an on-site isolated intermediate.

In most cases, risks stemming from the incorporation of the substance into an article are not in the scope of this screening report. Incorporation of a substance in articles has to be authorised, unless this use is exempted in accordance with Article 56(1) of REACH<sup>16</sup>. The incorporation process carried out in third countries is outside the scope of EU legislation (and REACH Authorisation). However, it should be noted that articles, if imported to the EU, are within the scope of this investigation. The incorporation is regarded to cover two type of uses<sup>17</sup>:

- a) The substance is incorporated into an article during its production, or
- b) The substance, alone or in a mixture, is incorporated into/onto an existing article (isolated or incorporated in a complex object) at a later stage (e.g., coatings, primers, adhesives, sealants) and become an integral part of the article (or of the complex object).

<sup>&</sup>lt;sup>16</sup> Q&A ID: 0564: <a href="https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/0564">https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/0564</a>. Note that ECHA will investigate for this report whether applications for authorisation/authorisation decisions cover the incorporation of the substance into an article and possible cumulative effects of the substance due to authorisations.

<sup>&</sup>lt;sup>17</sup> https://echa.europa.eu/documents/10162/23036412/articles\_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c