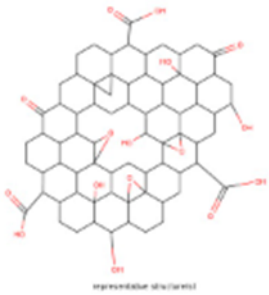
Justification Document for the Selection of a CoRAP Substance

EC/List number	CAS RN	Public Substance name	Chemical structure	Registration type
947-768-1	-	Reaction product of Graphite, acid-treated and potassium permanganate		Full

Authority: the Netherlands

Date: 19 March 2024

Revision history

Version	*Date*

Cover Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

1. Background

1.1 Analogue substances

EC/List number	CAS RN	Public Substance name	Chemical structure
801-282-5	1034343-98-0	Graphene	-
231-955-3	7782-42-5	Graphite	-

1.2 Overview of ongoing or completed other REACH and CLP processes & other EU legislation

No ongoing or completed REACH or CLP processes.

EC/ List number	Evaluation			CLH	Restriction	Authorisation
	CCH	TPE	Previously on CoRAP	Annex VI (CLP)	Annex XVII*	Candidate List/ Annex XIV
947-768-1	-	-	-	-	-	-

**Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40)*

EC/ List number	Other EU legislation	Previous legislation	Stockholm convention	Other
	PPP/ BPR	NONS/ RAR	POP	(e.g. UNEP)
947-768-1	-	-	-	-

2. Classification

You can find information on classification in the ECHA C&L Inventory database, which includes both harmonised classification (when available) and the notified self-classifications. (http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database]. The CLP Regulation and all published ATPs are available on ECHA website: http://echa.europa.eu/web/guest/regulations/clp/legislation .

EC/ List No	CAS RN	Public Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
947-768-1	-	Reaction product of Graphite, acid-treated and potassium permanganate	No harmonised classification	No self-classifications	Not classified (4)

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers. Therefore the number may differ from the C&L inventory which displays number of notifiers.

3. Tonnage and uses

3.1 Aggregated Tonnage

EC/ List No	Aggregated tonnage (as per ECHA dissemination website*)[1,2]
947-768-1	≥ 10 to < 100 tonnes

** The total tonnage band has been calculated by excluding the intermediate uses,- See also the Manual for Dissemination and Confidentiality under REACH (section 2.6.11): https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0*

3.2 Overview of the Uses

Main types of applications	List no 947-768-1 Key information
Industrial use	Use in polymers, coatings, fillers, putties, plasters, modelling clay, lubricants, grease, adhesives, sealants, inks, toners Use in metal and non-metal surface treatment products, and metal working fluids Use in manufacture of plastic products, electrical, electronic and optical equipment and machinery and vehicles.
Professional use	Similar uses as described above for industrial uses
Consumer Use	-
Article service life	Various article types (metal, wooden, plastics) used by workers and consumers
Intermediate use (if TII)	-
Formulation	Coating products, adhesives and sealants, metal surface treatments products, inks and toners, laboratory chemicals, lubricants and greases, metal working fluids and polymers.

[1] The total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

[2] Substance Infocard on ECHA's dissemination website accessed on 31 August 2023. NB. REACH registration data on ECHA's webpage has not been updated since 19 May 2023.

Justification for inclusion on the CoRAP

4.1 Legal basis

☒ Article 44(2)[3]

☐ Article 45(5)[4]

4.2 Identification of initial grounds of concern

Hazard-based concerns	
Suspected CMR	☐ Carcinogenic ☒ Mutagenic ☐ Reproductive toxicant
Potential ED	☐ Human Health ☐ Environment
Suspected Sensitiser	☐ Respiratory ☐ Skin
Suspected PBT/ vPvB Suspected PMT/ vPvM	☐ Persistent ☐ Bioaccumulative ☐ Mobile ☐ Toxic (as defined in section 4.3 below) ☐ very Persistent ☐ very Bioaccumulative ☐ very Mobile
Other suspected human health hazard(s) (e.g. STOT RE)	☒ (as defined in section 4.3 below)
Other suspected environmental hazard(s)	☐ (as defined in section 4.3 below)
Exposure/ risk-based concerns	
Wide dispersive use	☒
Consumer use	☐
Exposure of workers	☒
Exposure of sensitive populations	☐
Exposure of environment	☐
Cumulative exposure	☐
High RCR	☐
High (aggregated) tonnages	☐
Others (to be specified)	☐

[3] "The Agency shall use the criteria in paragraph 1 […]. Substances shall be included if there are grounds for considering (either on the basis of a dossier evaluation carried out by the Agency or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to human health or the environment."

[4] "A Member State may notify the Agency at any time of a substance not on the Community rolling action plan, whenever it is in possession of information which suggests that the substance is a priority for evaluation. […]".

4.3 Justification of the concern(s) – to be clarified under Substance evaluation

Existing data supporting the hazard-based concern and other relevant information to justify the inclusion in CoRAP

Reaction product of Graphite, acid-treated and potassium permanganate (List 947-768-1), hereafter 'the Substance', is an oxidized form of graphene. The registration of the Substance includes nanoforms of the material.

There is a concern on the potential toxicity of the Substance via inhalation. The available data are limited to short-term exposure studies (< 1 week) and are mainly performed by intratracheal instillation. The results are inconsistent, but several acute and/or sub-acute studies based on intratracheal instillation show that the Substance may induce pulmonary inflammation, acute phase response (systemic reaction to injury or toxicity) and genotoxicity. Furthermore, recent data suggest that the Substance is more genotoxic after repeated exposure than single exposure. Altogether, this raises concerns on the potential effects upon long-term exposure via inhalation. Currently, no subchronic or chronic toxicity studies with the Substance are available and thus potential long-term effects of the Substance cannot be assessed.

In addition, also genotoxicity needs further assessment based on the effects observed in the currently available data. Several in vitro comet assays, an in vitro micronucleus test and in vivo micronucleus test via intravenous exposure show a positive result. One in vivo comet assay with intratracheal exposure is available, showing a negative result. Further evaluation is needed, based on the exposure routes of the in vivo studies being not directly relevant and the lack of information on germ cells.

The available data show inconsistent results, which may be partly related to variations of the material tested. The Substance is a complex material, with variations in size, degree of oxidation, differences between batches, presence of impurities, etc. It is registered as UVCB. This complexity in the substance identity will be taken into account during assessment of the available data and potential risks.

Information to be potentially requested

Toxicity data on long-term exposure to the Substance are currently lacking; however, there are the above described indications of pulmonary and systemic effects observed in acute and sub-acute studies. Therefore, a potential request under substance evaluation could be a repeated dose sub-chronic toxicity study in rodents via inhalation exposure. Such a study may be combined with additional tests related to genotoxicity.

Possible follow-up (demonstrating the improvement of risk management measures)

EC/ List number	Harmonised C&L	SVHC	Restriction	Authorisation	Other
947-768-1	☒	☐	☐	☐	☐