JASTEC RoHS Exemption Request _ Exemption 12

Date of submission: 31 July 2019

1. Name and contact details

1) Name and contact details of applicant:

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2) Name and contact details of responsible person for this application (if different from above):

Company:	_____	Tel.:	_____
Name:	_____	E-Mail:	_____
Function:	_____	Address:	_____

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2. Reason for application:

Please indicate where relevant:

☐ Request for new exemption in:

☐ Request for amendment of existing exemption in

☒ Request for extension of existing exemption in

☐ Request for deletion of existing exemption in:

☐ Provision of information referring to an existing specific exemption in:

☐ Annex III ☒ Annex IV

No. of exemption in Annex III or IV where applicable: 12

Proposed or existing wording: Lead in metallic bonds creating superconducting circuits in MRI (Magnetic Resonance Imaging) or NMR (Nuclear Magnetic Resonance).

Duration where applicable:

Until 30 June 2028 (maximum 7 years validity).

☒ Other: The current wording is “Lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors”. JASTEC no longer uses cadmium and is concerned only with NMR and MRI and so proposes the revised wording given above.

3. Summary of the exemption request / revocation request

NMR spectrometers, used for chemical analysis, and MRI scanners, used for medical imaging, use powerful electromagnets made with superconducting wires that are connected to each other and to the power supplies using superconducting solder bonds. Soldering has been found to be the only consistent and reliable method for making electrical connections and solders based on lead are the only materials that have a sufficiently high critical field value (the maximum allowable field where superconductivity persists) of over 1 Tesla to be used within the electromagnet cryostat. All lead-free solder materials have much lower critical field values that are too small for use in this application.

JASTEC has carried out trials using lead-free solders as substitutes, but the measured critical current values (at which non-dissipative current flows) were too low and were smaller than the currents typically used for NMR and MRI. Research into alternative bonding methods is published, but this work is at an early stage and will take many more years and may prove to be unsuitable.

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4. Technical description of the exemption request / revocation request

(A) Description of the concerned application:

1. To which EEE is the exemption request/information relevant?

Name of applications or products: NMR (Nuclear Magnetic Resonance) spectrometers and MRI (Magnetic Resonance Imaging) including MRI/CT[1] , MRI/PET and MRI-guided radiation therapy medical imaging equipment

a. List of relevant categories: (mark more than one where applicable)

☐ 1	☐ 7
☐ 2	☒ 8
☐ 3	☒ 9
☐ 4	☐ 10
☐ 5	☐ 11
☐ 6	

b. Please specify if application is in use in other categories to which the exemption request does not refer: SQUID (Superconducting Quantum Interference Device) and FTMS (Fourier Transform Mass Spectrometer) detectors.

[1] CT = Computed Tomography and PET = Positron Emission Tomography.

c. Please specify for equipment of category 8 and 9:
   The requested exemption will be applied in
   ☒ monitoring and control instruments in industry
   ☐ in-vitro diagnostics
   ☒ other medical devices or other monitoring and control instruments than those in industry

2. Which of the six substances is in use in the application/product?
   (Indicate more than one where applicable)
   ☒ Pb ☐ Cd ☐ Hg ☐ Cr-VI ☐ PBB ☐ PBDE

3. Function of the substance: To make superconducting electrical connections to MRI and NMR superconducting magnet coils.

4. Content of substance in homogeneous material (%weight): 50 – 70% lead.

5. Amount of substance entering the EU market annually through application for which the exemption is requested: Estimated to be 1.2 tonnes per year.
   Please supply information and calculations to support stated figure.
   NMR: JASTEC estimate that 200 NMR superconducting magnets (120 of 400MHz, 40 of 500MHz and 40 of 600MHz) are sold in the EU annually and contain 0.3kg lead (400MHz), 0.7kg lead (500MHz) or 1.3kg lead (600MHz).
   MRI: Based on OECD data, BMI research "Worldwide medical devices market forecasts to 2021", annual sales of superconducting magnets for MRI sold in the EU are 600 per year. JASTEC estimate that the average amount of lead metal per MRI is 1.8kg.

6. Name of material/component: Solder alloy. JASTEC use a lead-bismuth alloy.

7. Environmental Assessment: _____
   LCA: ☐ Yes
   ☒ No

(B) In which material and/or component is the RoHS-regulated substance used, for which you request the exemption or its revocation? What is the function of this material or component?

NMR and MRI both use superconducting electromagnet coils, although the designs are different. The coils are made from niobium/titanium (NbTi) and niobium/tin (Nb_3Sn) alloy wires which are superconducting at temperatures below about 9 to 18K (NbTi has a Tc of 10K and Nb_3Sn has a Tc of 18.3K). MRI uses

NbTi superconductor wires only, but to achieve the highest possible magnetic field strength inside the bore of NMR spectrometers, a combination of NbTi is used for an outer coil with Nb_3Sn in an inner coil. Nb_3Sn is used for an inner coil as it has a higher critical field strength than NbTi, although NbTi wires are easier to make and use. The Nb_3Sn coil wires of NMR have to be bonded to the NbTi coil's wires using a superconducting material to ensure that entire conductor coil remains superconducting.

When the coil circuit is entirely superconducting, no energy is lost and consequently the magnetic field becomes very stable which allows sensitive measurements of MRI and NMR spectroscopy. If a normal resistive bond is used instead, then the magnet energy is dissipated at the resistive bond that would heat the adjacent superconductors above their transition temperatures (Tc) and the coil circuit loses superconductivity.

Superconducting solders for connecting magnet conductors need to stay superconducting at the operating temperature and magnetic field. At a reasonable distance from the magnet, the magnetic field decays to less than the critical field of lead-bismuth alloy. This makes lead-bismuth alloy suitable as a superconducting bonding material, whereas no other solder materials have a sufficiently high critical field to place them within a magnet cryostat.

To maintain a sufficiently low temperature to ensure that the electromagnet wires are superconducting, these are cooled with liquid helium which boils at 4.2K. The MRI and NMR coils are used to create a very powerful magnetic field which is used with MRI for imaging parts of the human body and with NMR for chemical analysis. The more powerful the magnetic field, the better the MRI image quality and the more detailed is the NMR spectrum. To obtain a powerful magnetic field, a large current is passed through the coil, typically of many 100s of amps. With this size of current, any electrical resistance would result in resistance heating that could raise the temperature of the bonds and the coil to temperatures where the materials are not superconducting and the temperature rise can destroy the coils. Heat generated is calculated from:

Power = current squared x resistance (I^2R)

In addition, magnetic field decay due to resistance in superconducting circuit is a problem since NMR and MRI require a highly stable magnetic field. If a superconducting bond has a small electrical resistance, it causes current consumption in the superconducting circuit and consequently reduces the current flow in the circuit.

As a result, it is essential that the materials used to make electrical connections to the superconducting coils are also superconducting materials; lead alloys are used because of the overall performance they provide (as explained below).

The superconducting alloys NbTi and Nb_3Sn are hard brittle materials that are difficult to make electrical connections. In MRI and NMR, these alloy wires are embedded in copper with many superconductor wires encased in copper which is then drawn down to the required thickness so that the NbTi and Nb_3Sn wires are present inside the copper cable as very thin wires. The simplest and most reliable method of making electrical connections to the ends of the coil is by soldering. In the soldering process, the copper matrix is removed and then the superconductor filaments are soldered tightly. Lead alloys such as lead-bismuth solders are ductile at low temperatures, are superconductors at liquid helium temperature in the presence of the strong magnetic field which arise when passing very large currents, and are sufficiently robust to withstand the severe vibrations that occur in the superconductors in the presence of the high magnetic fields of NMR and MRI.

MRI are used in hospitals for the generation of 3-dimensional images of the insides of human patients as well as of animals for veterinary examinations. MRI can image soft tissues such as the internal organs, muscles and blood vessels. MRI with the most powerful magnetic fields (1.5 and 3 Tesla are commonly used) require superconducting magnets.

NMR spectroscopy instruments are used for chemical analysis. Various designs are produced with a wide range of electromagnetic field strengths. NMR with less powerful magnetic fields are simpler and therefore cheaper to buy and use, and are suitable for analysis of relatively simple compounds. These might be used by students as well as professional researchers. NMR with powerful superconducting magnets can analyse more complex substances, mixtures of substances and substances present at low concentrations, but due to the greater skill and experience needed to use them, these tend to be used only by professionals.

MRI are usually made using single lengths of copper clad NbTi superconductor with electrical connections at each end, but more powerful magnets may have two or more lengths of NbTi connected by superconducting bonds. NMR however, especially those with high field strength of 10 Tesla, use Nb_3Sn (as well as NbTi) as this has a higher critical field, so can achieve more powerful magnetic fields than NbTi alone, although it is more difficult to make very low resistance bonds to Nb_3Sn wire[3]. NMR electromagnets will have multiple joints (one published example has 10 joints in a 9.4 Tesla NMR and passes 100 amps[3]) and to ensure that the magnetic field is very stable, the total electrical resistance of all of the joints must be extremely low. This is currently technically possible only by soldering with superconducting lead alloys.

MRI (and NMR) coils can experience severe vibration due to the effect of "gradient coils" that are placed around the parts of patient's being scanned. To prevent damage from vibration as well as the stresses that occur when coils are cooled from ambient to 4K, the coils are impregnated with resins that prevent movement that would otherwise cause damage to the superconducting coils.

When exemption 12 was originally added to Annex IV of the RoHS Directive, MRI and NMR manufacturers used an alloy that contains both lead and cadmium (Woods alloy). Research since then has found that lead alloys without cadmium are suitable (lead-bismuth is superior) and so cadmium is no longer used and so does not need to be included in the renewed exemption 12.

(C) What are the particular characteristics and functions of the RoHS-regulated substance that require its use in this material or component?

The bonding material used to make electrical connections to superconductor coils must have all of the following essential characteristics:

- High T_C, at least higher than the boiling point of liquid helium.
- Be a superconductor in the presence of a powerful magnetic field. (It should have a high critical field of at least higher than the magnetic field at the locations of the solder bonds, which is typically 1 Tesla.)
- Be a superconductor when passing many hundreds of amps and in the presence of a powerful magnetic field.
- Be reliable for >20 years when subjected to very large temperature changes and severe vibration.
- All bonds must be consistently good with zero electrical resistance at 4K.
- The bonding method must be suitable for connecting to NbTi and to Nb_3Sn.

Solders additionally must be:

- Ductile at low temperatures. This is important because there will be a large mismatch between the thermal expansion coefficients of the superconductor and the solder and, as the bonds are cooled to 4K, the stresses will cause de-bonding if the solder is not ductile.
- Melt at <400°C (to avoid damage to coil and resin bonding materials).
- Form strong bonds to copper, NbTi and Nb_3Sn without formation of thick layers of brittle intermetallic phases (which would cause failure of the bond).
- Forms bonds that are stable at 4K

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5. Information on Possible preparation for reuse or recycling of waste from EEE and on provisions for appropriate treatment of waste

1) Please indicate if a closed loop system exist for EEE waste of application exists and provide information of its characteristics (method of collection to ensure closed loop, method of treatment, etc.)

Some NMR and MRI are collected by the original manufacturers and are refurbished for reuse. However at end of life, when reuse is no longer possible, both NMR and MRI enter WEEE streams for recycling and so no closed loop exists for all of the bonds to superconducting electromagnets.

2) **Please indicate where relevant:**

☐ Article is collected and sent without dismantling for recycling

☒ Article is collected and completely refurbished for reuse

☒ Article is collected and dismantled:

☒ The following parts are refurbished for use as spare parts: Many of the component parts of NMR and MRI can be reused, but the lead alloy bonds to the superconducting coils are always recycled for materials recovery.

☒ The following parts are subsequently recycled: Any parts that are unsuitable for reuse as spare parts are recycled for materials recovery including the solder bonds to superconductor coils.

☐ Article cannot be recycled and is therefore:

☐ Sent for energy return

☐ Landfilled

3) **Please provide information concerning the amount (weight) of RoHS substance present in EEE waste accumulates per annum:**

☒ In articles which are refurbished: NMR and MRI that are refurbished for reuse so are not waste. End of life is delayed.

☒ In articles which are recycled: Sales of NMR and MRI have been stable for many years so we estimate about 0.5 to 1 tonnes of lead is recycled annually, although a more precise quantity cannot be measured as MRI and NMR are collected and recycled with other large equipment (as defined by the WEEE Directive).

☐ In articles which are sent for energy return ______

☐ In articles which are landfilled ______

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6. Analysis of possible alternative substances

(A) Please provide information if possible alternative applications or alternatives for use of RoHS substances in application exist. Please elaborate analysis on a life-cycle basis, including where available information about independent research, peer-review studies development activities undertaken

Research into substitute solders and alternative bonding methods for making electrical connections to superconductor wires has been published[2], [3].

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[2] For example, Superconducting Joints for Magnet Applications, Susie Speller et al, downloaded from https://stfc.ukri.org/files/superconducting-joints-for-magnet-applications/

Substitute solders

The essential requirement for a material used to make superconducting electrical connections to the superconducting electromagnet coils is that the bonding material can pass a high current with no loss (due to electrical resistance), at an operating temperature lower than its critical temperature (Tc) and at an operating magnetic field lower than the bonding material's critical field. Only a few metallic elements have Tc values that are significantly higher than the boiling temperature of liquid helium and one publication[4] lists only: lead, niobium (its alloys used for the electromagnet coil), technetium (a manmade element which is radioactive), lanthanum (Tc is only 4.87 K) and vanadium with a Tc of 5.46 K. Of these metals, only lead and its alloys are suitable for soldering to superconducting electromagnet cables. As bonds are usually immersed in liquid helium, they should not exceed 4.2K, however they are exposed to powerful magnetic fields from the electromagnets and so a high critical field values of the material is more important in NMR and MRI applications.

The critical temperatures and critical field strength values of metals and alloys with melting temperatures that are sufficiently low to be suitable as solders is published. Suitable metals with melting points below about 400°C are the elements and alloys of lead, tin, indium, cadmium and bismuth although some alloys also contain zinc, silver or other elements. Illustrative examples are listed in the table below.

[3] Persistent current joints between technological superconductors, Greg Brittles, et. al., article in Superconductor Science and Technology · September 2015

Table 1. Comparison of properties of elements and binary solder alloys[3]

Metal / alloy	**Tc critical temperature**	**Critical field strength**	**Comments**
Lead	7.19 K	80 mT	Suitable, but has lower critical field than PbBi alloy
Indium	3.41 K	28.15 mT	Tc and critical field are too low as below boiling temperature of He*
Tin	3.72 K	30.6 mT	Tc and critical field are too low*. Also, tin will undergo a phase transformation at low temperature and disintegrate (tin pest)
Zinc	0.86 K	5.4 mT	Tc is much too low*
Lead–bismuth ($Pb_{60}Bi_{40}$)	8.4 K	1770 mT	Suitable for MRI and NMR
Indium-tin ($In_{50}Sn_{50}$)	6.5 K	650 mT	Inferior performance to PbBi, but is the most promising lead-free substitute
Indium-bismuth ($In_{43}Bi_{57}$)	2.3 K	40 mT	Tc is too low*
Tin-lead ($Sn_{60}Pb_{40}$)	7.05 K	83.2 mT	Critical field is too low (and lead based)
Tin bismuth ($Sn_{43}Bi_{57}$)	2.25 K	38.3 mT	Both Tc and critical field are too low*

* Tc is below the boiling temperature of He (4.2 K).

Pure bismuth was not believed to be a superconductor, but recently superconductivity was discovered at 0.00053 K, which is much too low to be of any use in MRI or NMR, which operate at about 4 K. Cadmium has a Tc of 0.52 K and gallium of 1.08 K, so are also both unsuitable as metallic elements for bonding.

Lead has a critical temperature of 7.2 K and some additive elements such as arsenic, bismuth and antimony increase Tc, although arsenic is very toxic and antimony will make the alloy very hard and brittle, especially at low temperatures. Arsenic increases Tc to 8.4K at 10 atomic %[4].

What is most important for MRI and NMR however is the critical magnetic field, which decreases with increasing temperature. At about 4K, niobium has a thermodynamic critical field of 0.165T, lead of 0.07T, tin of <0.01T and indium is 0T, so lead is the most suitable solderable material in powerful magnetic fields for bonding[5]. Niobium cannot be used for bonding as its melting point is higher than that of copper and the superconducting niobium alloys. The critical current decreases as the critical magnetic field decreases. The performance of NMR and MRI increases as magnetic field strength increases and so it is important that a very large current can be used to generate a very powerful magnetic field and this depends on the choice of superconducting bond material.

Some research on ternary alloys has also been published. These tend to be multiphase alloys where each phase has different Tc and critical field values. Research results shows that In-Sn-Bi alloys have much smaller critical field values than Pb-Bi alloy[6].

Another limitation on bonding alloy is that it must be ductile at very low temperatures. This is because bonds are made between the solder and copper/niobium superconductor wire at about 200°C and then are cooled to the operating temperature of about 4K (-269°C). Copper and lead alloy solders will not have the same thermal expansion coefficient (e.g. copper is $17 \times 10^{-6} K^{-1}$, bismuth is $13 \times 10^{-6} K^{-1}$ and lead is $29 \times 10^{-6} K^{-1}$, although these values vary with temperature) and so as the bonds cool through ca.470°C, any mismatch in contraction on cooling will induce a stress on the bond. Unless relieved by the ductility of the solder, this could cause bond delamination and so failure would result (as copper/ NbTi is much less ductile than PbBi). Lead and its alloys with bismuth are relatively ductile at low temperatures and so are suitable bonding materials.

Alternative bonding methods

Diffusion bonding: Research into diffusion bonding has been published and this technique can be used to connect pairs of mechanically soft NbTi wires together, but it is not suitable for bonding to hard and brittle Nb_3Sn. Diffusion

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[4] Superconductors, chapter 4.2. downloaded from https://www.google.co.uk/search?ei=HZBwWruyHIT8gAaF17Qw&q=superconductors+4.2&oq=superconductors+4.2&gs_l=psy-ab.12...2010535.2019011.0.2021383.19.14.0.5.5.0.212.1646.8j5j1.14.0....0...1c.1.64.psy-ab..0.18.1633...0j0i67k1j0i131k1j0i131i67k1j0i10k1j33i160k1.0.fxjZhTBSCSM#

[5] http://www.kayelaby.npl.co.uk/general_physics/2_6/2_6_4.html

[6] See reference 2, slide 13, which shows the dependence on critical current on magnetic field strength comparing PbBi with InSnBi.

bonding occurs when two oxide-free metal surfaces are placed in contact, usually with a large contact force that deforms the material to create intimate metal to metal contact. Higher melting point metals bond more easily if heated as long as this does not cause excessive oxidation. Diffusion bonding is relatively easy with soft metals such as indium which can easily be bonded at room temperature with a fairly small force, but NbTi is much harder than indium and has a thin but very stable surface oxide that prevents diffusion bonding from occurring. Nb_3Sn also has a thin and stable oxide but being hard it requires a very high force to achieve an intimate metal to metal bond. Copper (from the supporting sheath) is first removed such as by dissolution in nitric acid or in a bath of liquid tin. Next, to enable diffusion bonding the surface oxide and any residual copper must be removed and this is possible only with hydrofluoric acid (HF). HF is very hazardous and is used under strictly controlled conditions by the semiconductor industry, but manufacturers always avoid using it wherever possible because skin contact has caused worker deaths and serious injuries[7]. Bonding requires a controlled contact force and very low electrical resistance values have been obtained, although results were found to be inconsistent, probably because very little diffusion bonding occurred. No successful diffusion bonding has been reported with Nb_3Sn.

Welding: Research using spot welding is published[3]. Bonding has been achieved with NbTi, but due to chemical reactions that occur at high temperature, this was not suitable for Nb_3Sn. Bonding between NbTi filaments is possible but only after removal of copper to expose the filaments. Filaments can be bonded to niobium foil or twisted together before bonding. Results with twisted wires showed that the critical current ratio (CCR) was only 10% of un-bonded wires, so is unsuitable.

Results showed that when copper sheet is used for thermomechanical support for the NbTi wires, copper infiltrates the NbTi and some oxidation also occurs but much higher CCRs were achieved. The report's authors state however, that high temperatures can negatively affect the nanostructure of the NbTi wires and detrimentally affect the superconducting properties. The authors conclude that welding is a promising technique but it will be difficult to use consistently in a production line to produce reliable bonds. Spot welding is not currently used commercially for NMR or MRI.

(B) Please provide information and data to establish reliability of possible substitutes of application and of RoHS materials in application

Substitute materials are technically impractical due to their properties as shown in table 1 and as explained in section 6. Research using diffusion bonding and

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7 For example, https://www.ncbi.nlm.nih.gov/pubmed/11494350 and https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4116323/

welding has given inconsistent results (with NbTi only), as explained above, so reliability is not assured.

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7. Proposed actions to develop possible substitutes

(A) Please provide information if actions have been taken to develop further possible alternatives for the application or alternatives for RoHS substances in the application.

Trials using InSnBi and SnBi solders as superconducting bonding materials have been carried out by JASTEC, but were unsuccessful as the bonds were found to have a small electrical resistance at liquid helium temperatures and the measured critical current was too low at only 30 – 40 amps to be practical for use in MRI and NMR (MRI and NMR typically use 100 – 1000 amps). Further research is needed to determine the cause of the small resistance as the cause is not clear, but the insufficiently high critical current (as predicted from published values in reference 2) will be difficult or impossible to overcome.

Published research using spot welding may be feasible for NbTi but not for Nb_3Sn, which is used for NMR. However, to date, this technique has not given consistent results and the process is possible only under controlled laboratory conditions.

Research with high temperature superconducting electromagnets for MRI and NMR is published[8], but as these are operated at liquid helium temperatures to achieve the optimum performance and the highest possible critical current[9], they are likely to also need to use lead alloy solders to make electrical connections in these NMR and MRI.

(B) Please elaborate what stages are necessary for establishment of possible substitute and respective timeframe needed for completion of such stages.

It seems to be very unlikely that a substitute solder will be identified because all low melting point metals and alloys that are suitable for solder bonding and which will create ductile bonds have been considered. Only alloys containing lead give sufficiently high magnetic field strength for use in NMR and MRI. All potential substitute materials have significantly lower Tc and critical field values compared with lead alloys so it appears that a substitute material does not exist.

Alternative bonding methods such as spot welding may eventually be possible, but this is far from certain. The influence of the magnetic behaviour of the superconductor on the shape of the magnetic field from the superconducting magnet is critical for achieving optimal performance of NMR and MRI. Any distortion of the magnetic field will impair MRI imaging and NMR analysis

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[8] For example, https://global-sei.com/technology/tr/bn66/pdf/66-09.pdf

[9] There are many publications describing NMR and MRI made with high temperature superconductors and all describe operation at liquid helium temperatures. For example, "*High-Temperature Superconducting Magnets for NMR and MRI: R&D Activities at the MIT Francis Bitter Magnet Laboratory*", Iwasa Yukikazu et al., http://dx.doi.org/10.1109/tasc.2010.2040073 and "*Present Status and Future Perspective of Bismuth-Based High-Temperature Superconducting Wires Realizing Application Systems*", Ken-ichi Sato et. al., Japanese Journal of Applied Physics 51 (2012) 010006 (see section 5).

sensitivity and accuracy. Therefore, even if better consistency can be achieved and the process scaled up for manufacturing the impact of the high temperature on the flux pinning nanostructure of the NbTi filaments needs to be resolved before commercialisation. Also, bonding of NbTi to Nb3Sn by welding is not technically possible. JASTEC estimate that this research will take at least 5 years and may not be feasible.

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8. Justification according to Article 5(1)(a):

(A) Links to REACH: (substance + substitute)

1) Do any of the following provisions apply to the application described under (A) and (C)?

☐ Authorisation

☒ SVHC
☒ Candidate list
☐ Proposal inclusion Annex XIV
☐ Annex XIV

☐ Restriction

☐ Annex XVII
☐ Registry of intentions

☒ Registration

2) Provide REACH-relevant information received through the supply chain.
Name of document: Lead registration details are available from https://echa.europa.eu/registration-dossier/-/registered-dossier/16063

(B) Elimination/substitution:

1. Can the substance named under 4.(A)1 be eliminated?

☐ Yes. Consequences? ______

☒ No. Justification: No suitable substitute materials or designs exist.

2. Can the substance named under 4.(A)1 be substituted?

☐ Yes.

☐ Design changes:
☐ Other materials:
☐ Other substance:

☒ No.

Justification: No suitable substitute materials or designs exist.

3. Give details on the reliability of substitutes (technical data + information): See section 6.

4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to
    1) Environmental impacts: _____
    2) Health impacts: _____
    3) Consumer safety impacts: _____

⇨ Do impacts of substitution outweigh benefits thereof? Not applicable to this exemption.
Please provide third-party verified assessment on this: _____

(C) Availability of substitutes:

a) Describe supply sources for substitutes: None exist.
b) Have you encountered problems with the availability? Describe: No issues with supply of metals.
c) Do you consider the price of the substitute to be a problem for the availability?
☐ Yes ☒ No because, substitutes do not exist.
d) What conditions need to be fulfilled to ensure the availability? See section 7 (B)

(D) Socio-economic impact of substitution:

⇨ What kind of economic effects do you consider related to substitution?

☐ Increase in direct production costs

☐ Increase in fixed costs

☐ Increase in overhead

☒ Possible social impacts within the EU. If this exemption is not renewed, hospitals will not be able to buy new MRI scanners and universities and research institutes would not be able to buy new high performance NMR spectrometers.

MRI: Currently, it is estimated that there are 7500 MRI in use in the EU[10] used to diagnose and treat the EU's population of over 500 million people. OECD data indicates that about 14 million MRI scans are carried out annually in the EU. As the currently used MRI become older and begin to fail and cannot be repaired, so become unusable, this number of scans will inevitably decrease as the number of usable MRI decreases, so that eventually, many millions of EU citizens will not have their illnesses diagnosed as early as possible or at all. As a result, some will die (e.g. due to detecting cancer later than is possible with MRI) and the treatment times for some patients will be longer (as they become more serious due to later diagnosis using less appropriate techniques). Longer treatment times will result in increased costs for hospitals (which EU governments will not fund) and also patients' outcomes may be inferior.

NMR: JASTEC estimate that there are about 3000 NMR spectrometers in the EU with superconducting magnets. These are used by research establishments such as for pharmaceuticals, food, chemistry and industrial product research. Many thousands of researchers at R&D laboratories and at universities will be at a very significant disadvantage compared with those at non-EU establishments and many will as a result lose their jobs. It is also inevitable that many company research laboratories will be forced to relocate outside of the EU in order to be able to use the best performing NMR and this will negatively impact on EU competitiveness and there would be a significant loss of jobs. R&D accounts for over 2% of GDP in the EU and employed 1.2% of the EU labour force in 2016[11], equivalent to 2.7 million jobs[12]. A significant proportion of these jobs would be at risk if exemption 12 is not renewed.

☒ Possible social impacts external to the EU: EU citizens may need to travel to non-EU countries to use MRI for medical treatment. Researchers and EU research facilities may relocate to non-EU countries.

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[10] https://data.oecd.org/healthcare/magnetic-resonance-imaging-mri-exams.htm

[11] GDP = Gross Domestic, data from Product from https://ec.europa.eu/eurostat/statistics-explained/index.php/Europe_2020_indicators_-_R%26D_and_innovation

[12] EU employment is estimated to be 228.7 million employees. https://www.statista.com/topics/4095/employment-in-europe/

☐ Other: _____

⇨ Provide sufficient evidence (third-party verified) to support your statement: See footnotes 10, 11 and 12.

9. Other relevant information

Please provide additional relevant information to further establish the necessity of your request:

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10. Information that should be regarded as proprietary

Please state clearly whether any of the above information should be regarded to as proprietary information. If so, please provide verifiable justification:

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