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Paris, 8 April 2020

For the attention of the responsible services of the European Commission, ECHA and the Member States competent authorities for REACH and CLP (CARACAL)

REVISED SPACE INDUSTRY POSITION 2020: *EXEMPTION OF PROPELLANT-RELATED USE OF HYDRAZINE AND OTHER LIQUID PROPELLANTS FROM THE REACH AUTHORISATION REQUIREMENT*

The purpose of this document is to state the revised common position of the European Space Industry on the exemption of propellant-related use of hydrazine (EC 206-114-9)[1] and a number of other liquid propellants for space applications from the authorisation requirement under Regulation (EC) No 1907/2006 (REACH). Hydrazine has been included in ECHA's candidate list on 20 June 2011 and may be prioritized for inclusion in Annex XIV of REACH at any time.

This paper has been prepared in the frame of the Hydrazine REACH Authorisation Task Force (HTF) of the European Space Industry, a splinter group of the Materials and Processes Technology Board of the European Space Components Coordination (ESCC MPTB). It reflects the best knowledge available from experts in their field, thanks in particular to the support of the following corporations

> *Airbus Defence and Space; ArianeGroup; Arianespace; AVIO Group; ELV SpA; GHC Gerling, Holz & Co. Handels GmbH; Nammo Westcott Ltd; OHB; Surrey Satellite Technology Ltd (SSTL); Thales Alenia Space (TAS)*

and space agencies

> *European Space Agency (ESA); Agenzia Spaziale Italiana (ASI); Centre National d'Etudes Spatiales (CNES); Deutsches Zentrum für Luft- und Raumfahrt e.V. (DLR)*

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[1] Including CAS Number 302-01-2 for the anhydrous form and CAS Number 7803-57-8 for the hydrated form.

EXECUTIVE SUMMARY

The present revision (the "revised position 2020") **maintains** the assessment and conclusions of the initial ASD-Eurospace Position Paper titled *"Exemption of propellant-related use of hydrazine from REACH authorisation requirement"* dated May 9th, 2012 (the "initial position 2012"), while **taking into account relevant updates** of space applications, relevant EU legislation, ECHA guidance, questions and answers and recent judgments of the Court of Justice of the European Union (CJEU), in particular the judgment of 10 September 2015 in case C-106/14 (see change history in Annex 5).

In addition, the assessment and conclusions for hydrazine have been **extended** during 2019 to the following liquid propellants (see Annex 3):

- **"MMH" - MonoMethyl Hydrazine** (CAS 60-34-4, EC 200-471-4);
- **"NTO" - Dinitrogen Tetraoxide** (CAS 10544-72-6, EC 234-126-4), including NTO as such and as part of MON-x (Mixed Oxides of Nitrogen) mixtures;
- **"UDMH" - Unsymmetrical DiMethyl Hydrazine** (CAS 57-14-7, EC 200-316-0).

Based on the assessments carried out, the European Space Industry is of the opinion that all propellant-related use of hydrazine, MMH, NTO (as such and as part of MON-x mixtures) and UDMH for space applications would be exempted from REACH authorisation subject to the criteria given in this paper, chiefly based on REACH Art. 56(4)(d) 2nd alt. *"use as fuels in closed systems"*. In addition, other REACH provisions limiting the scope of authorisation are in our view applicable to certain phases of the propellant-related use of hydrazine, namely the use outside the EU/EEA territory / in space, REACH Articles 56(3)1 and 3(23) for test applications and REACH Article 2(2) for the decontamination, cleaning of equipment and waste disposal steps.

The exemption position for hydrazine is summarised in the following diagram (Figure 1).

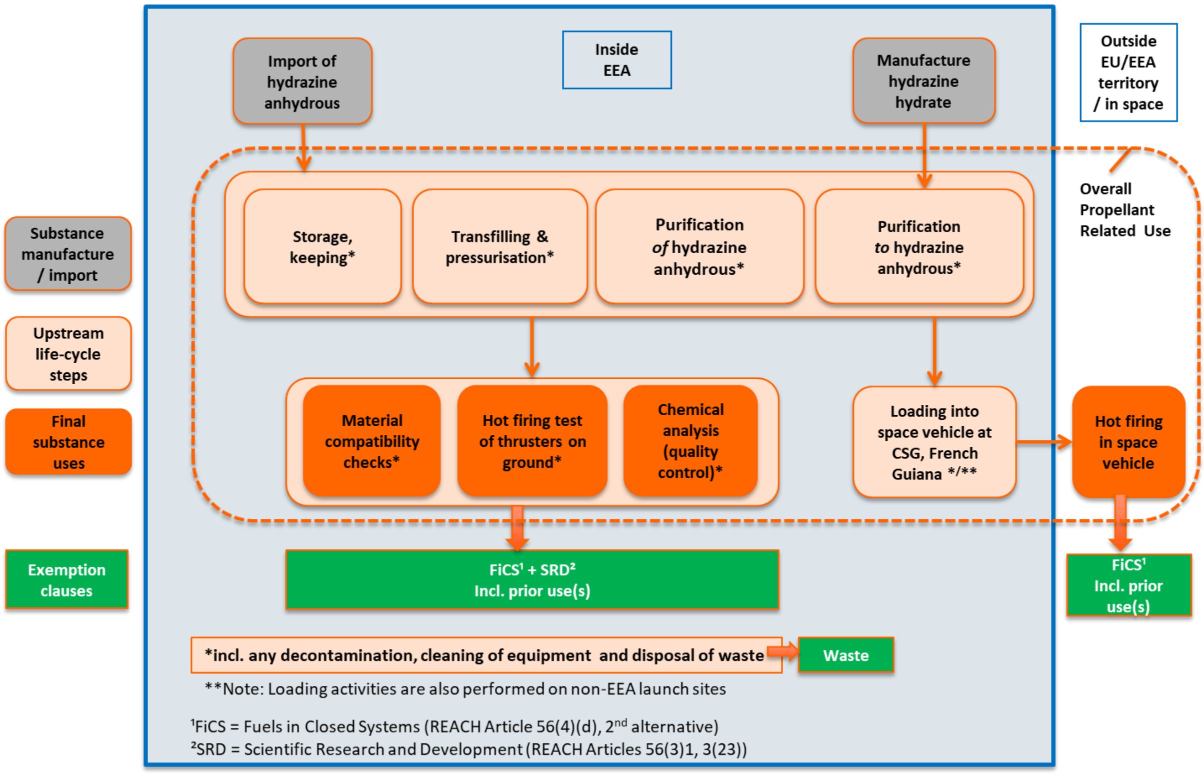

Figure 1 Exemption of propellant-related use in the European Space Industry from REACH authorisation

The exemption position applies in a representative way to MMH, NTO and UDMH, for which no further regulatory actions are proposed, according to ECHA's recent Chemical Universe list (publ. 4.12.2019).

The initial position 2012 for hydrazine was presented to the European Commission (DG Enterprise and DG Environment) at a meeting on 11 October 2012 in Brussels, requesting a legal clarification. The Commission has assured on several occasions to provide this clarification;[2] it is still pending. Eurospace stresses the crucial need to obtain the clarification should hydrazine be prioritised for Annex XIV, given the continued strategic importance of hydrazine and the other liquid propellants included in this paper and the need for long-term predictability with regard to the long lifecycles of space programmes.

Furthermore, it should be noted that Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work has introduced an EU binding Occupational Exposure Limit (OEL) for hydrazine. This substance- and workplace use-specific EU regulatory measure may now provide an independent additional ground for an exemption with regard to REACH Article 58(2), beyond the automatic exemption above based on the REACH legal text.

For the purpose of this Position Paper the term "space vehicle" refers to satellite systems, probes and space launch vehicles.

[2] Last answer given by Ms Bieńkowska on behalf of the Commission on 28 July 2016 to Parliamentary question E-003827-16; available at http://www.europarl.europa.eu/doceo/document/E-8-2016-003827-ASW_EN.html.

1. BACKGROUND: HYDRAZINE EXEMPTION STUDY 2011

Hydrazine (anhydrous) is a strategic component for satellite and launcher programmes. Due to its high purity quality required for space applications it is not comparable to other industrial uses and grades. In total, less than 20 tonnes per year of this "space-specified" hydrazine are currently being used within the European Union.

Against this background timely preparation for the required formalities to comply with the REACH authorisation process is imperative for conductance of current and future space operations.

Therefore a task force, open to all users of hydrazine in the European Space Industry, was set up in October 2011 under co-ordination of the European Space Agency (ESA) with the aim of determining the route to follow: Authorisation or exemption. In November 2011 a data evaluation questionnaire was circulated by Eurospace to all known EEA-based companies actually or potentially using hydrazine as well as to national space agencies (CNES in France and DLR in Germany), in order to obtain a complete understanding of the different handling steps and conditions of use, and allow an assessment of the applicability of REACH authorisation exemption clauses.[3] In parallel, an exemption feasibility study with similar scope was performed by one of the task force members, Airbus Defence and Space UK (former Astrium Satellites UK), supported by all major European satellite integrators.[4] Further, companies mapped their activities in the EEA supply chain for hydrazine step by step in process flows (see Appendices 5-7 to this paper).

During the assessment, the UK REACH and CLP helpdesk at HSE[5] and the German REACH-CLP Helpdesk at the Federal Institute for Occupational Safety and Health (BAuA),[6] commented on the case, and advised contacting European Commission and ECHA in order to obtain an authoritative clarification.

Based on the assessments carried out, the European Space Industry is of the opinion that all propellant-related use of hydrazine for space applications is exempted from REACH authorisation subject to the criteria given in this paper.

[3] The drafting of the questionnaire and assessment of exemption clauses based on the information received were carried out by the consultant REACHLaw Ltd (Finland), who was contracted by ESA for this purpose.

[4] Assisted by the consultancy ERA Technology Ltd (UK) and supported by the companies OHB, TAS and SSTL.

[5] Helpdesk references: 1412DXG11-2375 and 1412DLS11-0003.

[6] Helpdesk reference GZ: 5.0-720 34/04/2011.2172.

2. OVERVIEW OF PROPELLANT-RELATED USE OF HYDRAZINE IN THE EUROPEAN SPACE INDUSTRY[7]

For the purpose of this Position Paper the term "space vehicle" refers to satellite systems, probes and space launch vehicles.[8] Most space vehicles including telecommunication, Earth observation, navigation and scientific satellites as well as space launchers rely on hydrazine and/or hydrazine derivatives propellants. More specifically, major European programmes such as launchers (Soyuz, Vega), Galileo, GMES and other satellites produced for public agencies or for private operators use hydrazine.

Hydrazine anhydrous is a liquid, which is eventually used as an energetic material (propellant) in thrusters of launchers (upper stages) for satellites and satellites themselves (after separation from the launcher). The *function* of hydrazine-based propellant for space vehicles is to generate thrust for orbit change, attitude control and orbit manoeuvring.

Hydrazine is primarily used as mono-propellant, but may also be used in bi-propellant systems. *Mono*-propellant use means that hydrazine is decomposed using a catalyst under high temperatures in the propulsion system of the space vehicle, where hydrazine is **decomposed completely** into a hot gas (ammonia, nitrogen and hydrogen), which is emitted to the outside as exhaust through a nozzle. In *bi*-propellant systems hydrazine is **combusted completely** within a combustion chamber using an oxidizer to induce a hypergolic reaction, the combustion gases are ejected through a nozzle.

Prior to the target application as propellant, a number of handling steps and tests (together also referred to as *upstream life-cycle steps*) are necessary:

In some cases, the EEA supply chain for hydrazine anhydrous starts with its importation from outside EEA. Upon importation, samples of hydrazine are *chemically analysed* at different stages to determine conformance to the specifications for the propellant use.[9] If required, a *purification* process is applied in order to achieve compliance with the specification. *Transfer from one container to another* of hydrazine may be needed for delivery of the right quantity to the customer or the launch site; this also includes *pressurization with inert gases (N2, He)* of the drums for storage and transport. For the purpose of the final propellant application for European launches, hydrazine drums are shipped to Centre Spatial Guyanais (CSG), the European spaceport and launch facility near Kourou in French Guiana, where the EEA supply chain ends. At CSG, the substance is *loaded into the tanks of the space vehicle to be consumed during its flight.* Propellant loading activities are also performed on non-EEA launch sites.

Hot firing in space vehicles occurs only after launch vehicle take-off, thus outside the EU/EEA territory / in space.[10] No propellant is emitted from the space vehicle during the launch preparation activity on ground. All launching operations take place at CSG, a dedicated launch complex with restricted access

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[7] The information in this section and Annex 1 of this Position Paper has been obtained by consolidation of the data received from the entities that answered to the questionnaire circulated by Eurospace.

[8] Space vehicles are procured by governments, public institutions (military and civil) and commercial entities in Europe and worldwide.

[9] E.g. the US standard MIL-PRF-26536E.

[10] Within the scope of the *Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, including the Moon and Other Celestial Bodies*, in: United Nations Treaties and Principles on Outer Space, UN, New York, 2002.

following stringent French Guiana safety rules and the French Space Act (L.O.S.)[11] safety requirements. Launches from non-EEA launch sites follow the local launch site safety rules.

Furthermore, during the research and development as well as the qualification and acceptance phase of new space propulsion components hydrazine anhydrous is used on ground in EEA for the mandatory *hot firing test of thrusters* as well as *material compatibility checks*. Hydrazine use for these purposes or *chemical analysis* (see above) – altogether also referred to as *test uses* – normally leads to the consumption of the respective volumes.[12]

All handling steps and test uses are accompanied by specific procedures for *decontamination, cleaning of equipment and waste disposal*. Today, approx. 50-60 workers in total are involved in the handling of hydrazine anhydrous within the EU; they are specially trained and protected through adequate measures preventing exposure to the substance.

As an alternative to the import of hydrazine anhydrous – companies in the European Space Industry are today also securing the sourcing of hydrazine from within the EEA, thereby avoiding the weakness due to importation only from outside EEA which can be considered as a major concern for Europe's access to space. Sourcing anhydrous hydrazine within EEA is achieved by *purification from hydrazine hydrate* manufactured within EEA.

The following diagram (Figure 2) provides a graphical overview of all mandatory handling steps (upstream life-cycle) and tests with hydrazine in the EEA leading up to its final application as propellant in space vehicles.

[11] Loi n° 2008-518 du 3 juin 2008 relative aux opérations spatiales – « L.O.S. » (fully applicable for all launches after 01/01/2021), together with its associated technical regulation *"Arrêté du 31 mars 2011 relatif à la réglementation technique en application du décret n° 2009-643 du 9 juin 2009 relatif aux autorisations délivrées en application de la loi n° 2008-518 du 3 juin 2008 relative aux opérations spatiales"* ; available at https://www.legifrance.gouv.fr.

[12] During the test use or by destruction of residues from it.

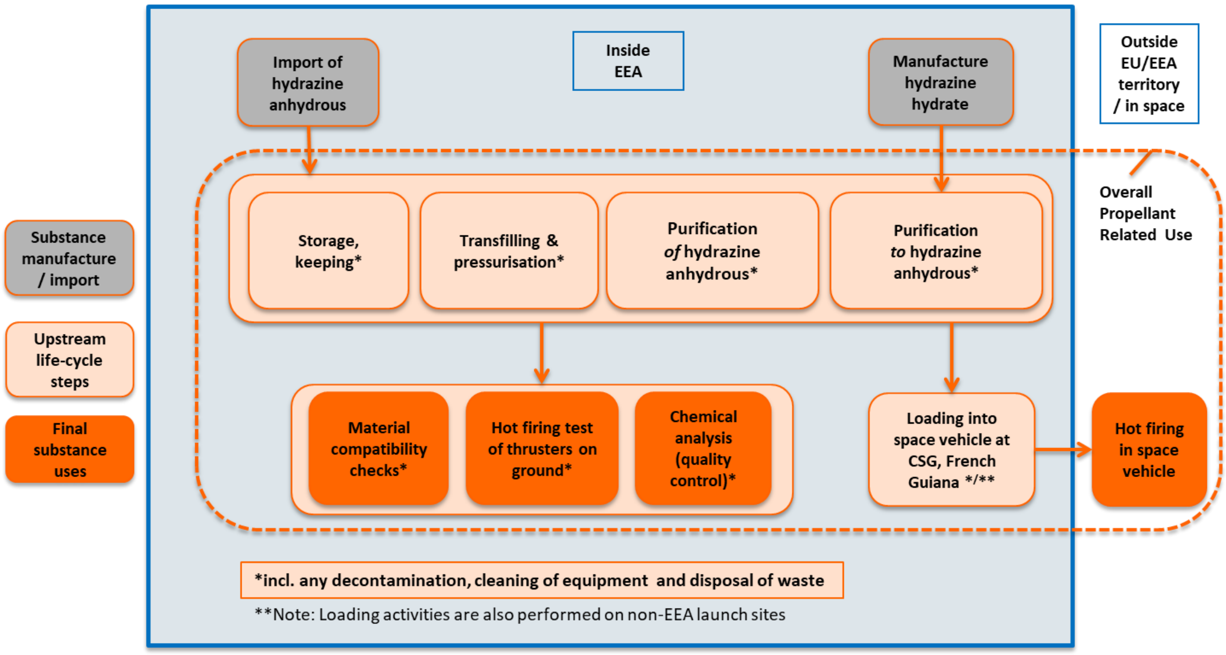

Figure 2 Propellant-related use of hydrazine in the European Space Industry

In terms of protection of human health and the environment, the guiding principle for all propellant-related use of hydrazine in the European Space Industry has always been prevention of worker exposure and environmental releases. To this end companies have been continuously implementing

- state-of-the-art technical hardware to enclose the substance during use;
- well-defined processes for all critical steps, that could harm health or environment;
- special facilities being equipped with monitoring and protection devices;
- training of highly skilled workers;
- other risk management standards, such as use of sophisticated personal protective equipment, for any case of accidental release;
- laws and regulations, which aim to protect worker safety and the environment.

The different steps of hydrazine propellant-related use in the European Space Industry outlined above as well as associated means of containment, exposure control and other risk management standards are explained in more detail in Annex 1 of this Position Paper, and are further illustrated in process flows relating to eventual use in satellites, launchers and ground test activities for thruster hot firing.[13]

[13] See Appendices 5-7 to this Position Paper.

3. LEGAL GROUNDS FOR THE EXEMPTION

In the opinion of the European Space Industry, all propellant-related use of hydrazine is exempted from REACH authorisation according to REACH Article 56(4)(d) 2nd alternative *"use as fuels in closed systems"*, subject to the criteria given hereafter.

In addition, other REACH provisions limiting the scope of authorisation are in our view applicable to certain phases of the propellant-related use of hydrazine, namely the use outside the EU/EEA territory / in space, REACH Articles 56(3)1 and 3(23) for test applications and REACH Article 2(2) for the decontamination, cleaning of equipment and waste disposal steps.

Furthermore, Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work may now provide an independent additional ground for an exemption with regard to REACH Article 58(2).

3.1. PROPELLANT-RELATED USE OF HYDRAZINE AS A CASE COVERED BY REACH ARTICLE 56(4)(D)

From the wording of REACH Article 56(4)(d) 2nd alternative two conditions can be derived:

- Use of substances as fuels
- Use in closed systems.

The fulfilment of these conditions for all propellant-related use of hydrazine on ground follows from the interpretations given hereafter.

3.1.1. USE OF SUBSTANCES AS FUELS

This first condition defines the principal scope of REACH Article 56(4)(d) 2nd alternative.

All identified handling steps and test uses of hydrazine on the ground are uses of a substance in terms of REACH Article 3(24). This also applies to the hot firing test of thrusters[14] and the hot firing in the space vehicle as the target application.[15] With regard to the latter, the CJEU has clarified with its judgment of 10 September 2015 in case C-106/14 that "articles" as defined in REACH Article 3(3) remain "articles" when incorporated into "complex objects". Therefore it is presently appropriate to base the assessment, whether the hot firing of the propellant in the space vehicle is the use of a substance[16], on the propellant tank as the container. Based on Section 2.3 of the ECHA guidance on requirements for substances in articles (SiA Guidance), as last updated through Version 4.0 in June 2017, this assessment leads to the conclusion that the hot firing of the propellant in the space vehicle is to be seen

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[14] Hydrazine is not becoming an integral part of an article / assembly thereof in this case, but remains (until consumption) a distinct substance flowing in the closed hydrazine supply system, i.e. from the tank - being an external part of the ground test facility - via the connection pipe into the thruster, see more detailed description of this use in Annex 1, Section 5. to this Position Paper.

[15] See detailed description in Annex 1, Section 1. to this Position Paper.

[16] Or the use of an article with an integral substance, as concluded in the initial position 2012 with reference to the space vehicle as a whole. However, as stated in the initial position 2012, the (exemption) conclusion would be the same if the target application was conceived as the use of an article with an integral substance.

as the **use of a substance in combination with an article / assembly (propellant tank / space vehicle at large)**. The propellant substance is specifically prepared (purified) to be able to function properly, and the propulsion system is specifically designed for the propellant. Clearly therefore, the shape/surface/design of the propellant tank as the container is not more relevant for the function than the chemical composition of the propellant. Please see Annex 2 of this Position Paper for further details supporting this conclusion.

Hydrazine anhydrous is also a *"fuel"* in the sense of REACH Article 56(4)(d). The term *"fuel"* is not defined in the REACH Regulation. In our opinion *"fuel"* is to be interpreted as a *material that is used as an energy source*. Further to this, Article 3(24) of Directive 2010/75/EU[17] contains a legal definition of *"fuel"* meaning *"any solid, liquid or gaseous combustible material"*.

Hydrazine anhydrous is a liquid combustible material, which is used as an energy source for space vehicle flights by means of hot firing, and hence a *"fuel"* in the sense of both definitions. Further, Directive 2009/43/EC (Annex, ML 8.c.4.a.)[18] acknowledges hydrazine anhydrous[19] as *"fuel"* explicitly. Any distinction between mono-propellant vs. bi-propellant systems would therefore be unjustified. Both processes are essentially hot firing under high temperatures in order to generate thrust. REACH Article 56(4)(d) 2nd alternative does not require that the mode of releasing the energy actually has to be combustion. Indeed, this may be required for REACH Article 56(4)(d) 1st alternative *"use as fuel in mobile or fixed combustion plants of mineral oil products"*, but combustion is not mentioned in the second alternative.

In order to be meaningful, the scope of REACH Article 56(4)(d) 2nd alternative should cover the *overall use* of the substance,[20] including the final substance application and all upstream life-cycle steps after its manufacture or import which are associated with the target application for which the substance is actually placed on the market by the manufacturer or importer. Presently, the target application is the hot firing of fuel-grade hydrazine anhydrous within the space vehicle. All identified handling steps and test uses after the substance import[21] up to the loading of the fuel into the propellant tank of the space vehicle are associated with the final propellant use and should therefore be covered by Article 56(4)(d) 2nd alternative. Hence, all these steps belonging to the *overall propellant-related use* should be covered by REACH Article 56(4)(d). This was now also explicitly confirmed by ECHA.[22]

Any other interpretation would be contrary to the comprehensive exemption for fuel uses introduced by the REACH legislator in Article 56(4), which includes fuel uses covered by existing specific Community

[17] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (Recast).

[18] Directive 2009/43/EC of the European Parliament and of the Council of 6 May 2009 simplifying terms and conditions of transfers of defence-related products within the Community.

[19] *"Hydrazine (CAS 302-01-2) in concentrations of 70 % or more."*

[20] In this sense also BAuA, answer of 21.2.2012, helpdesk reference GZ: 5.0-720 34/04/2011.2172: *"Es sind nicht die einzelnen Anwendungsschritte sondern die gesamte Verwendung zu betrachten."*

[21] Or after *manufacture* of hydrazine *hydrate* within EEA and supply to the EEA-based company that will then perform purification to fuel-grade hydrazine anhydrous for propellant use within the scope of REACH Article 56(4)(d) as a downstream user.

[22] See ECHA Q&A 1028 (Version 1.0 of 3.10.2018) : «[T]*he uses of a substance upstream, preceding "use as fuels in closed systems", are also exempted under the condition that the control of the risks – i.e., use in closed systems – is also pursued in the upstream life-cycle steps preceding the end-use as a fuel.* » ; available at https://echa.europa.eu/support/qas-support/qas.

legislation, namely *use as motor fuels covered by Directive 98/70/EC*[23] (lit. (c)), and further extends to fuel uses not covered by specific Community legislation, namely *uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems* (lit. (d)).

3.1.2. USE IN CLOSED SYSTEMS

The REACH Regulation does not explicitly define *"closed systems"*. In our opinion the term can be interpreted as follows:

> *"Closed system"* in the sense of REACH Article 56(4)(d) is a combination of state-of-the-art technical installations and procedures, that are designed to prevent exposure of humans to the substance or releases to the environment during its use to the maximum possible extent, resulting in a high integrity contained system where no or only little potential exists for exposures.[24] Adequate risk management standards are in place for any case of unintended release. A closed system can be established by applying the criteria for strictly controlled conditions in REACH Article 18(4), in association with the ECHA guidance on intermediates, to the relevant use.

Even though hydrazine propellant use may not be an intermediate use according to REACH Article 3(15), the definition in REACH Article 18(4) can in our opinion well be seen as a description of the conditions of a *"closed system"* in the context of REACH Article 56(4)(d), which can be practically established in connection with the ECHA guidance on intermediates.[25] Already the legal text implies that the system described in REACH Article 18(4) is equally understood as a closed system.[26] It should also be noted that in the frame of registration Article 18(4) applies fully to substances meeting the criteria of REACH Article 57, i.e. to substances which are (potentially) subject to authorisation.

The European Space Industry considers their systems for hydrazine propellant-related use as closed systems according to the aforementioned definition.

3.2. USES OCCURING OUTSIDE THE EU/EEA TERRITORY / IN SPACE

While the exemption is already fully justified based on REACH Article 56(4)(d) 2nd alternative (see above Section 3.1.), hot firing in space vehicles occurs only after launch vehicle take-off, thus outside the EU/EEA territory / in space. No propellant is emitted from the space vehicle during the launch preparation activity on ground. All launching operations take place at CSG, a dedicated launch complex

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[23] Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels.

[24] See also ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12: Use description, Version 3.0, December 2015, Table R.12- 11: Descriptor list for Process categories (PROC), PROC 16, Explanations and examples, p. 52.

[25] In this sense also BAuA, answer of 21.2.2012, helpdesk reference GZ: 5.0-720 34/04/2011.2172: *"Wenn Ihre Anwendung grundsätzlich durch Art. 56 Abs.4 d) abgedeckt wäre, könnte der Leitfaden herangezogen werden, um die Geschlossenheit zu belegen."*

[26] See REACH Article 18(4)(d): *"in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;".*

with restricted access following stringent French Guiana safety rules and the French Space Act (L.O.S.) safety requirements. Launches from non-EEA launch sites follow the local launch site safety rules.[27]

3.3. TEST USES AS A CASE COVERED BY REACH ARTICLES 56(3)1 AND 3(23)

From the wording of REACH Articles 56(3)1 and 3(23) setting out an exemption for substance uses in Scientific Research and Development (abbreviation *"SRD"*) two conditions can be derived:

- Use of substances in any scientific experimentation, analysis or chemical research (Section 3.3.1. below)
- Carried out under controlled conditions in a volume less than one tonne per year per legal entity (Section 3.3.2. below).

While the exemption is already fully justified based on REACH Article 56(4)(d) 2nd alternative (see above Section 3.1.), the additional fulfilment of the SRD exemption conditions for all test uses of hydrazine on the ground – including *hot firing test of thrusters*, *material compatibility checks* and *chemical analysis*[28] – follows from the interpretations given hereafter.[29]

3.3.1. USE OF SUBSTANCES IN ANY SCIENTIFIC EXPERIMENTATION, ANALYSIS OR CHEMICAL RESEARCH

All test uses with hydrazine on ground in EEA are *substance uses* in terms of REACH Article 3(24).[30]

ECHA has recognized early on that the SRD exemption can cover activities for monitoring/quality control purposes:[31]

- *SRD activities can cover analysis for monitoring or quality control purposes;*
- *Therefore, in principle a substance may be exempt from authorisation if used, on its own or in a mixture, in analysis for monitoring and quality control purposes, for instance, in order to monitor the presence or concentration of that substance or other substances;*
- *Only substances used directly for research or analytical purpose, whether on their own, in mixture or in conjunction with analytical equipment, can benefit from the SRD exemption. This excludes from the exemption any substances forming an integral part of an analytical device.*

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[27] See Section 2.

[28] See detailed descriptions of these uses in Annex 1, Sections 3. – 5. to this Position Paper.

[29] ECHA has also explicitly confirmed that the use of hydrazine as laboratory chemical and the use for hot firing tests in the aerospace industry can be regarded as SRD and therefore as being outside the scope of authorisation, see ECHA, Prioritisation assessment results of the Candidate List substances assessed - Substances included in the Candidate List by January 2018 and not yet recommended for inclusion in Annex XIV, 5 September 2018, available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_cl_substances_sept_2018_en.pdf.

[30] See already above Section 3.1.1.

[31] See for example Responses to Comments Document (RCOM) on ECHA's Draft 3rd Recommendation for Trichloroethylene (EC number: 201-167-4) of 20 December 2011, pages 3 and 4. The applicability of the SRD exemption to analytical activities such as monitoring and quality control has now been generally confirmed by ECHA, see Q&A 0585 (Version 1.2 of 3.10.2018) ; available at https://echa.europa.eu/support/qas-support/qas.

All test uses in question are activities for monitoring or quality control purposes:

- During *chemical analysis*, samples of hydrazine anhydrous are analysed in order to monitor its purity and to determine conformance with a standard (e.g. MIL-PRF-26536E), i.e. whether it has the required quality for use in space vehicles. Hydrazine is also used for catalyst reactivity verification.
- *Material compatibility checks* are carried out during the development and qualification phase of new space propulsion components (e.g. ECSS-E-ST-35-10C). The purpose of the testing is to determine compatibility of materials used in hydrazine propulsion systems (e.g. elastomeric and metal materials, sealing). To this end the materials are stored in very small quantities of hydrazine liquid (e.g. <500 ml). Hence, hydrazine is directly used in analysis for monitoring and quality control purposes, in order to monitor the impact of hydrazine on these materials. It is not necessary and not required by the wording of REACH Article 3(23), that the substance is itself the object of the analysis (see also ECHA comment above *"or other substances"*).
- *Hot firing test of thrusters* means hot firing of hydrazine for testing purposes when developing new thrusters as well as during the qualification and acceptance phase to approve new designs of thrusters.[32] As already highlighted, the hydrazine cannot be seen as an integral part of the test specimen or ground test facility equipment, but is used as a distinct substance which is flowing in the hydrazine supply system and hence is used in conjunction with the technical hardware necessary for the testing.

To the extent handling steps are necessary prior to the actual SRD activity (e.g. transfilling into smaller containers, storage or purification), they are in our opinion equally covered by the scope of the SRD exemption, because they are upstream life-cycle steps for the SRD use.[33] This was now also explicitly confirmed by ECHA.[34]

3.3.2. CARRIED OUT UNDER CONTROLLED CONDITIONS IN A VOLUME LESS THAN ONE TONNE PER YEAR

The REACH Regulation does not explicitly define *"controlled conditions"*. In our opinion the term can be interpreted as follows, taking into account ECHA's SRD guidance, Q&A and responses to comments on its draft 3rd recommendation for substances to be included in Annex XIV:[35]

> *"Controlled conditions"* in the sense of REACH Article 3(23) are a combination of technical installations, procedures and risk management standards that provide a coherent system to limit exposure of humans to the substance or releases to the environment during the scientific experimentation, analysis or chemical research, which takes into account the intrinsic properties of the substance, notably those leading to the inclusion in Annex XIV. Such *"controlled*

[32] See overview of different purposes of hot firing testing in Annex 1, Section 5. to this Position Paper.

[33] See corresponding reasoning other than relating to the specific aspects of the use as fuel in Section 3.1.1.

[34] See ECHA Q&A 1030 (Version 1.2 of 3.10.2018) : «[T]*he uses of a substance upstream preceding an exempted end-use in SRD are also exempted in quantities of the substance ending up in SRD (i.e. under 1 t/y per user)* […] *which, during the upstream life-cycle, are handled and/or used under controlled conditions*» ; available at https://echa.europa.eu/support/qas-support/qas.

[35] See for example ECHA Q&A 1030 (previous footnote), referring to « *an activity which is delimited by a certain level of control of risks* » ; Responses to Comments Document (RCOM) on ECHA's Draft 3rd Recommendation for Trichloroethylene (EC number: 201-167-4) of 20 December 2011, page 4, footnote 1.

> *conditions"* may be established by applying the tighter criteria for *"strictly controlled conditions"* in REACH Article 18(4), in association with the ECHA guidance on intermediates, to the relevant use.

In other words – according to ECHA – "controlled conditions" can be understood to mean that procedures and measures are in place to minimise (where information on the hazards is not available) or control (when the hazards are known) exposure and potential risks from exposure of humans and the environment to the substance. This may include, for example, limitation of uses to qualified persons having access to the substance, or collection and disposal of waste.[36]

The European Space Industry considers their conditions for test uses of hydrazine as controlled according to the aforementioned definitions.

3.4. DECONTAMINATION, CLEANING OF EQUIPMENT AND WASTE DISPOSAL STEPS AS A CASE OF REACH ARTICLE 2(2)

If not already covered as an integral part of the overall use exempted according to REACH Article 56(4)(d) and/or REACH Articles 56(3)1 and 3(23), *decontamination, cleaning of equipment and waste disposal* involving hydrazine are in our opinion regarded as waste treatment, which is done in accordance with the waste legislation, and hence not downstream uses under REACH.[37] According to Directive 2008/98/EC on waste, which has replaced Directive 2006/12/EC, *'waste' means any substance or object which the holder discards, or intends or is required to discard;"* (Article 3(1)). In our opinion accidental and unexpected spillage or release and disposal of un-used leftovers of hydrazine which are subject to specific cleaning or decontamination procedures, are by definition already waste from the moment of spillage, release or being left over, as the user *"intends or is required to discard"* them.

3.5. OEL UNDER DIRECTIVE (EU) 2017/2398 AS A CASE FOR REACH ARTICLE 58(2)

While the present position suggests that an exemption for any space propellant-related use of hydrazine from authorisation is already automatically applicable by means of interpreting the REACH legal text (Sections 3.1. – 3.4. above), an exemption of similar scope could also be introduced via REACH Article 58(2), should hydrazine be included in Annex XIV in the future.

REACH Article 58(2)1 stipulates that *"uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Union legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled."*

Presently, Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to

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[36] ECHA, Guidance on Scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD), Version 2.1, October 2017, Section 3.1, p. 8; available at https://echa.europa.eu/guidance-documents/guidance-on-reach.

[37] See ECHA, Guidance on registration, Version 3.0, November 2016, Section 2.2.2.4, p. 26; available at https://echa.europa.eu/guidance-documents/guidance-on-reach.

carcinogens or mutagens at work has introduced an EU binding Occupational Exposure Limit (OEL) value for hydrazine.[38]

Such an OEL could fulfil the criteria of REACH Art. 58(2), as it constitutes specific EU level legislative minimum requirements relating to the protection of health and safety of workers (OEL) for a specific substance (hydrazine) and use (workplace uses). Indeed, the judgments of the CJEU confirm that an EU binding OEL for a specific substance according to Directive 2004/37 is within the scope of REACH Article 58(2).[39]

Therefore, Directive (EU) 2017/2398 in association with REACH Article 58(2) would constitute an independent additional ground for an exemption for space propellant-related use of hydrazine.

4. FURTHER INFORMATION

This Position Paper and the assessments on which it is based have been made following collection of relevant use-related information from industry through careful analysis of the legal text of REACH and other relevant EU legislation, taking into account ECHA's latest guidance, Q&A, responses to comments documents on its previous draft Annex XIV recommendations and recent Court of Justice of the European Union (CJEU) judgments. The Position Paper may be further updated in light of future changes of use cases, EU legislation, new interpretations by the CJEU, the European Commission or new ECHA guidance.

Annexes to the Position Paper

- Annex 1: *Descriptions of propellant-related use of hydrazine in the European Space Industry*
- Annex 2: *Categorisation of hot firing in space vehicles according to ECHA SiA Guidance (2017)*
- Annex 3: *Extension of position to liquid bi-propellants MMH, NTO/MON-x and UDMH*
- Annex 4: *List of key acronyms*
- Annex 5: *Change history with view of the initial position 2012*

Appendices to the Position Paper

The following documents relating to this Position Paper are collected in a separate zip file:

- *1 - European Space Agency (ESA) letter of support (ref. D-TEC/2012.70), May 25th, 2012.*
- *2 - CNES letter of support (N/Réf.: IGQ//QC 2012. 08319), May 30th, 2012.*
- *3 - Answer dated of German REACH-CLP Helpdesk at the Federal Institute for Occupational Safety and Health (BAuA), helpdesk reference GZ: 5.0-720 34/04/2011.2172, February 21st, 2012.*

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[38] The Directive, which was to be transposed by Member States by 17 January 2020, foresees a limit value for hydrazine (EC No 206-114-9; CAS No 302-01-2) of 0,013 mg/m^3 and 0,01 ppm², together with a skin notation (indicating the possibility of significant uptake through the skin).

[39] Judgment of the General Court of 25 September 2015 in case T-360/13, VECCO and others vs European Commission, especially par. 47 *"*[t]*he mere fact of requiring occupational exposure limit values … constitutes a minimum requirement possible within the meaning of Article 58(2) of Regulation No 1907/2006"*; and related appeal case: Judgment of the Court of 13 July 2017 in case C-651/15P, especially par. 35 *"the term 'specific legislation' used in Article 58(2) of the REACH Regulation must be interpreted as referring, at the very least, to any directive or regulation laying down rules particular to the substance concerned."*

- *4 - Answer of the UK REACH and CLP helpdesk at HSE, helpdesk references: 1412DXG11-2375 and 1412DLS11-0003, December 14th, 2011.*
- *5 - Hydrazine Process Flow - European Satellite Suppliers (EEC Launch Facility), April 27th, 2012.*
- *6 - Hydrazine Process Flow - European Launch provider (EEC Launch Facility), April 26th, 2012.*
- *7 - Hydrazine Process Flow – Ground Test Activities for Thruster Hot Firing, April 27th, 2012.*
- *8 - DLR letter of support, June 29th, 2012.*

Note: *The Appendices 1-8 were already available and submitted to the European Commission in connection with the initial position 2012 and are included as a reference for this update of the position paper. The exemption-relevant contents of these submissions have **not** changed. Therefore, the material contents of the documents were not updated as part of the present revised position 2020. For minor updates in relation to Appendices 5-7 please see Annex 5.*

Kind regards,

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ANNEX 1: DESCRIPTION OF PROPELLANT-RELATED USE OF HYDRAZINE IN THE EUROPEAN SPACE INDUSTRY

This Annex details the different steps of hydrazine propellant-related use subject to the present Position Paper as well as associated means of containment, exposure control and other risk management standards.[40] *The information is a consolidation of data that have been collected from actual and potential users of hydrazine in the European Space Industry in the frame of the Hydrazine REACH Authorisation Task Force between November 2011 and February 2012.*[41]

1. HOT FIRING IN SPACE VEHICLES (TARGET USE)

Hydrazine anhydrous is a liquid, which is eventually used as an energetic material (propellant) in thrusters of launchers (upper stages) for satellites and satellites themselves (after separation from the launcher). The *function* of hydrazine-based propellant for space vehicles is to generate thrust for orbit change, attitude control and orbit manoeuvring.

The substance is primarily used as mono-propellant, but may also be used in bi-propellant systems. *Mono-propellant* use means that hydrazine is decomposed using a catalyst under high temperatures in the propulsion system of the space vehicle, where hydrazine is decomposed completely into a hot gas (ammonia, nitrogen and hydrogen),[42] which is emitted to the outside as exhaust through a nozzle.[43] In *bi-propellant* systems hydrazine as a fuel component is combusted completely within a combustion chamber using an oxidizer to induce a hypergolic reaction, the combustion gases are ejected through a nozzle.

Compatibility of hydrazine with materials used in the units (valves, tanks, thrusters) of the propulsion systems is critical for achieving its function throughout the space mission. Hydrazine propulsion technology is based on more than 50 years of space experience resulting in a very well understood technology with a very high degree of heritage and reliability.

Hot firing in space vehicles occurs only after launch vehicle take-off, thus outside the EU/EEA territory / in space. No propellant is emitted from the space vehicle during the launch preparation activity on ground. All launching operations take place at CSG, a dedicated launch complex with restricted access following stringent French Guiana safety rules and the French Space Act (L.O.S.). Launches from non-EEA launch sites follow the local launch site safety rules.[44]

The entire system is controlled thoroughly (tightness, functional and measurement tests) prior to fuelling of the tanks. Propulsion systems are designed to comply with the launch site safety requirements and international recognised norms such as MIL-STD-1522A and ECSS-E-ST-32-02C. Multiple

[40] See further the illustration of these steps in separate process flows relating to eventual use in *satellites*, *launchers* and *ground test activities for thruster hot firing* in Appendices 5-7 to this Position Paper.

[41] The data evaluation questionnaire and consolidation of data received were carried out by the consultant REACHLaw Ltd. (Finland), who was contracted by ESA for this purpose.

[42] With no hydrazine present.

[43] See ECHA, Annex XV dossier for Hydrazine, February 2011, p. 51, for more details about the mono-propellant use.

[44] See Section 2.

independent barriers (diaphragm of the tank, various valves, electrical barriers) are built and tested in the propulsion system against inadvertent hydrazine losses.

2. FILLING INTO THE TANK OF THE SPACE VEHICLE ("LOADING")

The filling with hydrazine for the target use in space vehicles is carried out at a dedicated filling station from a pressure drum directly to the propellant tank(s) by gas pressurising, through a tube or flexible directly connected to the drum. The gas pressure pushes out the liquid from the drum to the tank. The hydrazine fuelling equipment is designed as a closed system consisting of the following stages: Pressure drum – piping/flexible – control valves – propellant tank.

The loading of hydrazine for European launches always takes place at Centre Spatial Guyanais (CSG), the European spaceport and launch facility near Kourou in French Guiana. For non-European launches, the loading takes places on the respective non-EU/EEA launch site, following the local launch site safety rules.

All fuelling process steps are designed to protect worker safety and environment, and are described in detail in the relevant procedures (available with the corresponding fuelling service provider). These include for example:

- The loading of hydrazine always takes place in a dedicated room equipped with specific monitoring tools and rules for such propellant operations.
- The ground hardware used to fill the space vehicle is designed to comply with the launch site / testing facility safety requirements and national laws.
- All ground filling equipment is proof and leak tested before each activity, as is the space vehicle.
- All liquid and gas lines are monitored during valve opening and liquid flow to verify that the closed system is leak-tight.

Workers are highly skilled and regularly trained. Workplace and workers are monitored by gas detectors. Workers always wear special personal safety equipment like hermetic scape suits or breathing helmets, both with independent breathing air supply, and protective clothes as precaution when fuelling the space vehicle. Emergency processes and facilities are on standby if required and are constantly checked from a specific safety control room next to the fuelling facility during filling operations.

The filling facility is connected with a waste air treatment facility / gas washer equipment, which serve to remove any residual vapour of hydrazine and notably include dedicated neutralization systems.[45]

In exceptional cases, the loading process is reversed (*unloading*), e.g. for qualification purposes, using the same ground hardware, processes and workers.

3. CHEMICAL ANALYSIS

Quality control of the hydrazine needs to be carried out, before it can be used within the space vehicle. Anhydrous hydrazine that is used by the EU space sector needs to comply with accepted procurement standards [e.g. US standard MIL-PRF-26536E]. This standard describes the purity grades of anhydrous hydrazine, i.e. the acceptable composition of hydrazine propellant for space applications. The purpose of the analysis is to confirm conformance to the standard. To this end, a low amount of hydrazine (in any case far below 1 tonne per year per downstream user) will be used for chemical analysis.

[45] Potential remaining of hydrazine will normally be classified as waste and no further usage applies, see 11. of this Annex.

All analysis is covered by analytical procedures (chromatograph, spectrograph, etc.) that are solely undertaken in a closed environment (glove box/fume cupboard) thereby precluding worker exposure.

Workers are trained chemists. Workplace and workers are monitored by gas detectors. Workers always wear special personal safety equipment. At the end of the testing hydrazine is destroyed.[46]

4. MATERIAL COMPATIBILITY CHECKS

Material compatibility checks using hydrazine are carried out during the development and qualification phase of new space propulsion components (e.g. ECSS-E-ST-35-10C). The purpose of the testing is to determine compatibility of materials used in hydrazine propulsion systems rather than testing of the hydrazine itself (i.e. its suitability as fuel). Hydrazine is tested for compatibility against various materials (e.g. elastomeric and metal materials, sealing). To this end the materials are normally stored in very small quantities of hydrazine liquid (e.g. <500 ml), in any case far below 1 tonne per year per downstream user.

All analysis is covered by analytical procedures that are solely undertaken in a closed environment (glove box/fume cupboard) precluding any atmospheric exposure. The storage of materials in hydrazine takes place under controlled conditions (temperature, pressure).

Workplace and workers are monitored by gas detectors. Workers always wear special personal safety equipment. At the end of the testing hydrazine is generally destroyed.[47]

5. HOT FIRING TEST OF THRUSTERS ON GROUND

During the research and development as well as the qualification and acceptance phase for thrusters hydrazine is used for hot firing on ground in a dedicated test facility. Test facilities are currently located in Germany and UK. Hydrazine usage for test of thrusters is currently below 1 tonne per year per downstream user performing these tests.

The hot firing test, which may relate to mono-propellant (mainly) as well as bi-propellant thrusters, generally results in the total consumption (decomposition/combustion) of hydrazine, just like the hot firing in space vehicles (see above under 1.).

The test specimen is a mechanical rig which contains some measurement sensors, short connection pipes/flexibles, electrical connectors for the thruster-valve and the thruster itself, i.e. complete thruster or thruster assembly (feedline, valve, injector/catalyst chamber, thrust chamber, nozzle).

Hot firing is performed mainly *under vacuum conditions* in a vacuum test cell. Only for dedicated test purposes a *sea level testing* may be performed. Sea level testing uses in principle the same set-up as for the vacuum testing, just the vacuum installation (cell, piping, pumps) is missing.[48]

The hydrazine supply system is designed as a closed system consisting of the following stages: Pressure drum - piping - control valves – test specimen. Unlike loading into propellant tanks of space vehicles, supply of hydrazine into the test specimen is an integral part of the hot firing testing operation. Ground

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[46] Any residues are collected and sent to an authorised waste treatment plant, see 11. of this Annex.

[47] See previous footnote.

[48] Sea level testing using hydrazine is currently not performed in EU, but may be conducted again in the future under closed system / controlled conditions as defined in this Position Paper (Sections 3.1.2. and 3.3.2.).

facility tanks are simple pressure fed cylinders (whereas flight tanks can have a membrane, pressure fed or bladder designs), which are part of the ground test facility; they are designed and certified in accordance with the IMDG/ADR/RID rules or applicable pressure system safety regulations.

The different purposes of thruster testing are summarized in the following table.

Purposes of hot firing test of thrusters on ground

Form of thruster testing	Description of purpose
Research and development testing	Testing may relate to: New/modified and non-production thruster engine, fundamental investigations and principles (injector concepts, cooling concepts, new materials, etc.), multiple configurations and test protocols to determine new future product designs
Qualification testing	Testing of a thruster to demonstrate performance and lifetime abilities of a production class of engine. Thruster is subjected to various conditions to simulate expected operational limits in space. Hot firing has to show that the thruster will withstand operation conditions out of the acceptance specifications (margin tests).
Acceptance testing	Testing of a production engine to demonstrate functionality and acceptable performance levels for customer approval requirements. Testing includes standard on/off sequenced test firing to meet quality/customer specifications and to demonstrate correct workmanship.

From an exposure point of view there is no difference between the different forms of thruster testing. Under normal conditions and using standard controls, no worker exposures or releases to the atmosphere would occur because of the decomposition or combustion process during hot firing.

- This applies notably to the main case of *testing in vacuum test cells*. Under vacuum the exhaust will be collected in a closed vacuum system and sucked out by mechanical pumps. The exhaust gas will be treated with a scrubber or gas washer equipment. Thus, any small amounts of contaminated exhausts from the hot firing remain in a closed system. The contamination of the vacuum test cells is checked permanently by gas monitors. In case of an unexpected contamination of the vacuum test cell the equipment is cleaned by water and the water or cleaning tools are handled as contaminated waste.
- In case of *sea level testing* using hydrazine there is no release of hydrazine to the environment as it is fully consumed due to the oxidiser lead used for such hot fire tests.

Safety procedures are applied for all working steps and general test site safety procedures are in place. All hot firing is performed at dedicated test sites with dedicated licenses and restricted access under stringent safety conditions and governmental supervision.

Workers are highly skilled and regularly trained. Workplace and workers are monitored by sensors to detect hydrazine leakage. Workers, who could potentially be exposed to hydrazine, always wear special personal safety equipment.

6. FILLING INTO CONTAINERS, TRANSFER FROM ONE CONTAINER TO ANOTHER ("TRANSFILLING")

Hydrazine is transferred by pressurisation from one transport container (pressure drum, cylinder or other receptacle which can be used for transportation) to another ("transfilling"). This is necessary to deliver the right quantity to the customer.

The final transfer from pressure drum to propellant tank for flight ("loading") has already been addressed above under 2.

During pressurization/de-pressurization the gases will be dissolved by gas washer and highly efficient neutralization equipment. The remaining contaminated solution will be disposed (waste) and treated in a neutralization plant.

Workers are highly skilled and regularly trained. Workplace and workers are monitored by gas detectors. Workers always wear special personal safety equipment like gasmask and protective clothes as precaution.

7. PRESSURIZATION WITH INERT GASES (N_2, HE)

After filling of the drums with hydrazine they are pressurised by inert gases for storage and transport to customers or the launch site. The overpressure prevents any particle, oxygen or humidity contaminating the hydrazine.

The pressurization step can also be regarded as one (final) stage of the transfilling use described above under 6.

During pressurization/de-pressurization the gases will be dissolved by gas washer and highly efficient neutralization equipment. The remaining contaminated solution will be disposed (waste) and treated in a neutralization plant.

Workplace and workers are monitored by gas detectors. Workers are highly skilled and always wear special personal safety equipment like gasmask and protective clothes as precaution.

8. STORAGE, KEEPING

Hydrazine is stored in containers (pressure drums, transfer tanks, etc.) in dedicated areas under controlled conditions, with no likelihood of exposure. Containers are certified according to transport regulations (IMDG, RID, ADR) or applicable pressure system safety regulations. Periodic inspections of the containers as well as pressure & leak tightness check are carried out regularly.

9. PURIFICATION OF HYDRAZINE ANHYDROUS

End users of hydrazine anhydrous for hot firing in space vehicles require high purity grade, which has hydrazine content above 99%.[49] Purification of hydrazine anhydrous to a higher grade for final hot firing purposes may therefore be necessary. However, the imported hydrazine anhydrous can already be used as fuel if the required quality is sufficient (e.g. so called "monograde").

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[49] See ECHA, Annex XV dossier for Hydrazine, February 2011, p. 21.

The purification is based on a physical "cleaning" process and is not manufacture (chemical synthesis), i.e. the substance hydrazine is not chemically modified.

Purification is carried out into certified containers through gastight tubes. Neither exposure of workers nor releases to the environment occur during purification.

Workplace and workers are monitored by hydrazine detectors. Workers always wear special personal safety equipment.

10. PURIFICATION OF HYDRAZINE HYDRATE

By the time of the initial position 2012, anhydrous hydrazine had only been imported from non-EEA manufacturers. However, as access to space is strategic for the EU, sourcing hydrazine from outside of EEA has been a major concern; this supply was a weakness for European space programmes. Therefore, secure sourcing of hydrazine anhydrous on the European market by means of obtaining it in EEA from hydrazine hydrate sourced from EU manufacturers by purification for space propellant use only is now also carried out. In this case purification of non-fuel-grade hydrazine hydrate to obtain fuel-grade hydrazine anhydrous is carried out by EEA-based companies.

The starting material is hydrazine hydrate, which cannot be used as space propellant without further purification. Purification means separation of hydrazine and water through distillation and crystallisation to generate fuel-grade high purity hydrazine anhydrous. Similarly to purification of hydrazine anhydrous, purification of hydrazine hydrate is basically a physical "cleaning" process and is not a manufacture (chemical synthesis), i.e. the substance hydrazine is not chemically modified.

All handling and purification steps with hydrazine are done in closed systems (no release to air, soil and water, no contact with the substance for the users). Workers are highly skilled;[50] they will be protected by choosing the right protective clothing and equipment and releases to air will be excluded through use of proper gas cleaning systems. The working environment will be monitored by sensors.

11. DECONTAMINATION, CLEANING OF EQUIPMENT AND DISPOSAL OF WASTE

Decontamination, cleaning of equipment and waste disposal are mandatory process steps associated with the respective main handling steps of hydrazine, which are described above. They can therefore be regarded as integral (final) stage of the respective main handling steps of hydrazine described above.

Equipment to be cleaned includes e.g. the Fuelling Ground Support Equipment [FGSE], containers, test thrusters, personal protective equipment, cleaning items (such as cloths/rags) or Draeger tubes used for hydrazine detection.

The main activities in this respect include:

- Waste air treatment / gas washer equipment connected to the space vehicle filling facility or ground test facility, which serve to remove any residual vapour of hydrazine and notably include dedicated neutralization systems.
- Flushing of equipment or pipework with water or other substances; contaminated water/other substance will be disposed (waste) or treated in a neutralization plant. Equipment is flushed with water in a sealed condition before being dismantled.

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[50] Companies doing the purification of hydrazine hydrate have already been manufacturers of MMH or downstream users of hydrazine (anhydrous).

- Following hot firing testing of thrusters standard cleaning / decontamination protocols for the rocket engine are followed.
- Potential residuals of hydrazine are normally classified as waste and no further usage applies. Such residuals are collected and disposed (waste) under certified control.

Workplace and workers are monitored by sensors to detect hydrazine leakage. Workers always wear special personal safety equipment.

ANNEX 2: CATEGORISATION OF HOT FIRING IN SPACE VEHICLES ACCORDING TO ECHA SIA GUIDANCE (2017)

Further to Section 3.1.1. of this Position Paper, this Annex details the revised categorisation as the use of a substance (the propellant) in combination with an article / assembly for the hot firing in space vehicles according to Section 2.3 of ECHA's SiA Guidance, as updated.[51]

According to REACH Article 3(3) *article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.* An object made up of more than one article joined or assembled together with each other is referred to as a "complex object" in the SiA Guidance, rather than an article of its own.[52] Substances or mixtures contained in such an object are either considered as integral parts of an "article" or remain a substance – in combination with an article as such or in a complex object. This decision should be made based on the legal text (REACH Article 3(3) and – even though not legally binding – the decision criteria in Section 2.3 of the ECHA's SiA Guidance.

Categorisation according to the ECHA SiA Guidance:

***Step 1**: Define the function of the object in line with section 2.1.* [of ECHA SiA Guidance 2017] *The term "function" in the article definition should be interpreted as meaning the intended purpose for which an object is to be used. It may be helpful to look at the result of using an object and pay less attention to the quality of the result. For example, the purpose of a printer cartridge is to bring ink onto paper. A higher degree of technical sophistication of the object "printer cartridge" may improve the functioning and the quality of the result but it does not change the function as such. An object may have multiple functions and they may have different levels of importance (e.g. "accessory function"), hence all these functions must be taken into account when deciding whether an object is an article or not.*

The object in question is the *propellant tank as the lowest level component article / assembly that contains the propellant.* This follows from the judgment of the CJEU of 10 September 2015 in case C-106/14, according to which "articles" as defined in REACH Article 3(3) remain "articles" when incorporated into "complex objects" (principle "once an article – always an article"). The previous assessment in the initial position 2012, which conducted the analysis exclusively on the *space vehicle as a whole*, cannot be maintained because it referred explicitly to the previous interpretation by ECHA, the Commission and the majority of EU Member States that the complex object as a whole (as supplied) is regarded as an "article".[53] However, this interpretation was overruled by the CJEU in case C-106/14.

The function, i.e. purpose of the propellant tank, is that of a container for the controlled delivery of the propellant for hot firing. The function of *hydrazine* propellant is to serve as an *energy source to generate thrust* for the space vehicle.

Step 2**: Compare the importance of physical form and chemical characteristics for achieving the object's function.* ***If it can be unambiguously concluded that the shape, surface or design of the object is more relevant for the function than its chemical composition, the object is an article. *If the shape, surface or design is of equal or less importance than the chemical composition, it is a substance or mixture.*

[51] Version 4.0 (June 2017).

[52] ECHA, SiA Guidance (2017), Section 2.4, p. 22. The concept of a "complex object" was introduced based on the judgment of the European Court of Justice of 10 September 2015 in case C-106/14.

[53] See ECHA, SiA Guidance, version 2, 1 April 2011, Section 2. and 4.4., describing e.g. a laptop as a complex « article ». This version is now outdated.

The propellant substance is specifically prepared (purified) to be able to function properly,[54] and the propulsion system is specifically designed for the propellant. Hydrazine can only execute its function in a propulsion system specifically tailored to it in terms of design and materials used. Clearly therefore, the shape/surface/design of the propellant tank as the container is not more relevant for the overall function than the chemical composition of the propellant, but it is of less importance. Hence, the propellant unambiguously remains a distinct substance when loaded into the tank and thereafter when being delivered from the tank for hot firing purposes.

Therefore the assessment could already stop here, because the propellant use for space propulsion has been confirmed to be the use of a substance in combination with an article / assembly (propellant tank / space vehicle at large).

However, to clarify the conclusion made, the ECHA decision flow according to Section 2.3 of the SiA Guidance (2017) shall be further analysed.[55]

If it is not possible to unambiguously conclude *whether the object fulfils the REACH definition of an article or not, a deeper assessment is needed; for this* ***proceed with step 3****.* *Steps 3 to 6 were developed to support a deeper assessment for certain large (sub)groups of objects with common features. Note that they do not cover all possible objects, therefore, they may not allow reaching a final conclusion for a particular object under assessment. In such cases, the assessment needs to take into account other specific considerations that will allow answering the question in step 2 in the workflow above.*[56]

At this point, Steps 3 to 6 appear not to be applicable to a propellant tank that is part of a very complex object (space vehicle). The examples discussed in the SiA Guidance were rather developed for much simpler / different objects (see e.g. Table 6: Summary of borderline cases described in Appendix 3) and are not comparable to the present case of a space vehicle propellant. As said above, the propellant substance is specifically prepared (purified) to be able to function properly for its final application, and the propulsion system is specifically designed for the propellant. Thus, **specific considerations** apply, that allow answering the question in step 2 to the effect that the final propellant use is a substance use.

The assessment still continues only to clarify the conclusion.

Step 3: *Determine if the object, which may be constructed in a very simple or highly sophisticated manner, contains a substance or mixture that can be physically separated from the object (e.g. by pouring or wringing out). The substance or mixture in question, which can be solid, liquid or gaseous, can be enclosed in the object (like e.g. the liquid in a thermometer or the aerosol in a spray can), or the object can carry it on its surface (like e.g. a wet cleaning wipe).* ***If this applies to the object, proceed with step 4****, [...].*

As already indicated above, the object *propellant tank* contains the substance hydrazine that can be physically separated from the tank by means of emptying it.

[54] See Annex 1, especially Sections 3, 7, 9 and 10.

[55] It is acknowledged that ECHA has stated in a Note to CARACAL on the « EDA Member States Common Position on Ammunition Classification under REACH » of 20/12/2017: « If one reaches a conclusion at a certain step (e.g. step 2), one should not proceed to the next steps unless stated otherwise.» (see page 7, comment number 5 of Annex I to the Note). However, in our opinion the verification of the conclusion made according to subsequent relevant steps is presently useful, as it enhances clarity about the conclusion reached.

[56] This wording was added for the SiA Guidance update to version 4.0 in June 2017.

As the answer to step 3 is positive, the assessment should continue with step 4.

> ***Step 4:*** *For determining whether the chemical content of the object is an integral part thereof (and therefore the object as a whole is an article as defined under REACH) or if it is a substance/mixture for which the rest of the object functions as a container or carrier material, the following indicative questions should be answered:*
> *Question 4a: If the substance/mixture were to be removed or separated from the object and used independently from it, would the substance/mixture still be capable in principle (though perhaps without convenience or sophistication) of carrying out the function defined under step 1?*
> *Question 4b: Does the object act mainly (i.e. according to the function defined under step 1) as a container or carrier for release or controlled delivery of the substance/mixture or its reaction products?*
> *Question 4c: Is the substance/mixture consumed (i.e. used up e.g. due to a chemical or physical modification) or eliminated (i.e. released from the object) during the use phase of the object, thereby rendering the object useless and leading to the end of its service life?*
> ***If these questions can predominantly be answered with yes (i.e. 2 or 3 out of 3) rather than no, then the object should be regarded as a combination of an article (functioning as a container or a carrier material) and a substance/mixture.***

Answer to Question 4a: **YES** – As a matter of fact, the propellant *is* removed from the propellant tank and used independently from it for the purpose of hot firing. This being said, hydrazine requires a catalyst for its exothermic decomposition. It furthermore requires a thrust nozzle to accelerate the exhaust gases in order to generate the thrust.

Answer to Question 4b: **YES** – The *propellant tank* acts as a container or carrier for release or controlled delivery of hydrazine. Hydrazine is not released or delivered by the space vehicle and is consumed internally only.

Answer to Question 4c: **YES** – Indeed hydrazine is consumed internally within the space vehicle through hot firing during its use phase. Once the tank is empty, it has no further purpose.

Given that the questions 4a-c can predominantly be answered with yes (i.e. 3 out of 3), then the object should be regarded as a combination of an article (functioning as a container or a carrier material) and a substance/mixture. The further questions as part of step 5 do therefore not apply.

Finally, this conclusion is also supported by ECHA's proposal for a generic categorisation of energetic materials, ammunitions and related products under REACH.[57] According to this proposal "military and non-military ammunition or similar products that **produce an effect** such as heat, light, sound, gas, smoke, shock wave/blast effect or a combination of these are categories as a substance/mixture in a container or carrier. As mentioned above, the function of hydrazine propellant is to serve as an energy source **to generate thrust** for the space vehicle. Hence, the function is directly linked to the chemical reaction (decomposition / combustion reaction) that takes place during the hot firing.

The critical consequences of this categorisation are:

1. **The hot firing of hydrazine in space vehicles is the use of a substance in combination with an article / assembly (propellant tank / space vehicle at large).**
2. **The exemption according to REACH Article 56(4)(d) 2nd alternative "use as fuels in closed systems" clearly applies to such substance use and upstream life-cycle steps.**

[57] See ECHA Note to CARACAL, footnote 61, Annex II, page 12 and 13 (Group 2). Only products of Group 4 comprising « military and non-military ammunition or similar products designed to launch/propel a projectile or a device » are proposed by ECHA to be articles with an integral substance/mixture. However, the latter has so far only been formally acknowledged for « ammunition cartridges that are designed to launch a projectile (i.e. a bullet) », see ECHA Q&A ID 1059, Version 1.0 of 22/12/2017, available at https://echa.europa.eu/support/qas-support/qas; these are not comparable to the present case.

ANNEX 3: EXTENSION OF POSITION TO OTHER LIQUID PROPELLANTS MMH, NTO/MON-X AND UDMH

In January 2019 the HTF participants agreed to re-activate and extend the scope of their REACH task force in order to broaden the exemption assessment previously done on hydrazine by including also the following substances due to their hazardous properties:

- **"MMH" - MonoMethyl Hydrazine** (CAS 60-34-4, EC 200-471-4);
- **"NTO" - Dinitrogen Tetraoxide** (CAS 10544-72-6, EC 234-126-4), including NTO as such and as part of MON-x (Mixed Oxides of Nitrogen) mixtures;
- **"UDMH" - Unsymmetrical DiMethyl Hydrazine** (CAS 57-14-7, EC 200-316-0).

The objective of this extension was to confirm, whether a common baseline on exemption from an assumed REACH authorisation requirement can be established for these substances, thus covering all liquid propellants used in the European Space Industry today. It is important to note that these substances and hydrazine are not interchangeable in their use nor derived from one another. Also, MMH, NTO and UDMH are not on the REACH Candidate list today; instead ECHA recently confirmed for all of them that no further regulatory actions are proposed.[58]

1. SECOND EXEMPTION STUDY 2019

The 2nd exemption study 2019 followed the same pattern as previously done on hydrazine. In April 2019 REACHLaw issued a survey to HTF participants to gather relevant information on the uses (handling steps in EU/EEA and final application) of MMH, NTO and UDMH in order to determine whether they may benefit from a similar exemption from REACH authorisation as already established for hydrazine. At the same time, update needs for the initial position 2012 on hydrazine were identified. Survey responses were received from 11 entities, including companies and space agencies. The final exemption study report was delivered to HTF in November 2019.

2. OVERVIEW OF PROPELLANT-RELATED USE OF MMH, NTO/MON-X AND UDMH

MMH, UDMH and NTO/MON-x (oxidizer) are used as **bi-propellants** for space vehicles (satellite and launcher applications), which react with each other in a combustion chamber and decompose totally into uncritical substances upon end use.

MMH with NTO/MON-x are used basically for all bi-propellant orbital propulsion systems of commercial and institutional space vehicles. Current notable applications include, but are not limited to, telecommunication platforms, earth observation and scientific missions, ESA missions, "Heinrich-Hertz-Satellite" (a German institutional spacecraft funded through Germany's national space programme). MMH is used and sold a pure product. In contrast to hydrazine, which is used in high quantities for non-space applications (in particular as hydrazine hydrate), the numbers of uses and the yearly quantity of MMH consumed outside the Space Industry are very limited.

UDMH with NTO/MON-x is used as bi-propellant fuel for upper stage applications on *launchers* (only): VEGA AVUM and Soyuz-Fregat. The use is for space applications only (as fuel for rocket motors) by one European space company acting as downstream user. Less than 1 tonne per year of UDMH are currently used in the European Space Sector.

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[58] See ECHA, Chemical Universe List, publ. 4.12.2019, available at https://echa.europa.eu/universe-of-registered-substances.

NTO being the oxidizer can be used as such (on its own) but is commonly used as part of MON-x (Mixed Oxides of Nitrogen) mixtures. "X" indicates the % of Nitric Oxide (NO) inside NTO; **MON-1** and **MON-3** mixtures are currently in commercial production.

The possible future use of these bi-propellants for **defence projects** was also mentioned.

The different steps of propellant-related use as well as associated means of containment, exposure control and other risk management standards have been found to be either identical or very similar to those described for Hydrazine (see Annex 1). Survey respondents unanimously describe the substance supply system as a closed system (pressure drum – piping – control valves – spacecraft thrusters).

Only the following peculiarities in relation to handling were reported:

- **Purification** (see point 9 and 10 of Annex 1) is only done for NTO, not for MMH/UDMH.
- The preparation of a MON-x mixture through addition of NO gas is a second production step.
- There are **some chemical/physical differences for MON**, e.g. in terms of ADR/IMDG transportation classification which may result in some differences on the detailed technical level (e.g. types of respirators during handling, exposed materials to the propellant [i.e. vessel design]). However, according to the survey responses all propellants are handled in closed loop. Essentially the same steps are taken for all identified uses, same RPE/PPE is used, same exposure controls, etc.

3. CONCLUSIONS OF SECOND EXEMPTION STUDY

The 2nd exemption study concluded that it is possible to pursue a similar exemption as in the case of hydrazine for MMH, UDMH and NTO/MON-x. Hence, all propellant-related use of these substances for space applications could be exempted from REACH authorisation pursuant to **REACH Article 56(4)(d) 2nd alternative**, if the substances were included in Annex XIV in the future. Additional clauses (such as SRD) may be applied in analogy to the hydrazine case to back-up the exemption claim covering part of the use cases.

The survey feedback unanimously suggests that it is possible to view the handling and supply systems for these substances as closed systems. Furthermore, not only MMH and UDMH,[59] but also NTO/MON-x (oxidizer) can be seen "as fuels" used in terms of this clause. Bi-propellant systems, of which NTO/MON is an essential part, work through reaction in a combustion chamber (see Section 2 in the main document). As a hypergol (in contact with a the other bi-propellant), NTO/MON does combust, and as a result is also an energy source for thrust if reacting with the other bi-propellant fuel. The difference in the use is only at thruster level, whereas the on-ground handling by the space downstream users is more or less the same.

Therefore, a full reference to the legal grounds for the exemption for hydrazine (see Section 3.1. – 3.4. in the main document) is possible and valid.

[59] MMH and UDMH are also included in the list of *"Pyrotechnics", **fuels** and related substances,* […] pursuant to Directive 2009/43/EC of the European Parliament and of the Council of 6 May 2009 simplifying terms and conditions of transfers of defence-related products within the Community, see ML8 lit. c point 4 a, b and d; see latest consolidated version of 5.3.2018 at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009L0043-20180305.

ANNEX 4: LIST OF KEY ACRONYMS

ADR	Accord européen relatif au transport international des marchandises Dangereuses par Route: The European Agreement concerning the International Carriage of Dangerous Goods by Road (1957). Further details: Link
ASI	Agenzia Spaziale Italiana
CJEU	Court of Justice of the European Union
CNES	Centre National d'Etudes Spatiales
CSG	Centre Spatial Guyanais The European spaceport and launch facility near Kourou in French Guiana
DLR	Deutsches Zentrum für Luft- und Raumfahrt
ECHA	European Chemicals Agency
ECSS	European Cooperation for Space Standardization
ESA	European Space Agency
EEA	European Economic Area: All Member States of the European Union (EU) incl. French Guiana, as well as in Norway, Iceland and Liechtenstein. REACH applies in the EEA territory. Switzerland, Turkey or Russia are not part of the EEA.
FiCS	Fuels in Closed Systems (as per REACH Article 56(4)(d))
FGSE	Fuelling Ground Support Equipment
GMES	Global Monitoring for Environment and Security (see ESA website)
HTF	Hydrazine REACH Authorisation Task Force of the European Space Industry
IMDG	International Maritime Dangerous Goods: A Code accepted as an international guideline to the safe transportation or shipment of dangerous goods or hazardous materials by water on vessel. Further details: Link
L.O.S.	Loi n° 2008-518 du 3 juin 2008 relative aux opérations spatiales, the French Space Act
MIL-PRF	US military performance standard
MIL-SPEC	US military specification of technical requirements for purchased materials or products
MIL-STD	US military standard

MMH	MonoMethyl Hydrazine (CAS 60-34-4, EC 200-471-4)
MON-x	Mixed Oxides of Nitrogen mixtures. “X” indicates the % of Nitric Oxide (NO) inside NTO: MON-1 and MON-3 mixtures are currently in production.
MPTB	Materials and Processes Technology Board
NO	Nitric Oxide
NTO	DiNitrogen Tetraoxide (CAS 10544-72-6, EC 234-126-4)
OEL	Occupational Exposure Limit
PPE	Personal Protective Equipment
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006)
RID	The Regulation concerning the International Carriage of Dangerous Goods by Rail. Further details: Link
RPE	Respiratory Protective Equipment
SiA	Substances in Articles
SRD	Scientific Research and Development: Any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year (REACH Article 3(23))
SVHC	Substance of very high concern (see REACH Article 57)
UDMH	Unsymmetrical DiMethyl Hydrazine (CAS 57-14-7, EC 200-316-0)

ANNEX 5: CHANGE HISTORY WITH VIEW TO THE INITIAL POSITION 2012

The following table shows the history of relevant changes in the revised position 2020 with view to the initial position 2012. Minor changes (e.g. to the latest ECHA guidance version, where contents have remained the same) are not included.

Reference in revised position 2020	**Change with view to the initial position 2012**
Cover page (*new*)	Updated list of HTF participants
Executive summary	Revised to include the rationale for the update and summarise the revised position 2020 for hydrazine and other liquid propellants Added reference to the 2012 request for legal clarification to the European Commission and the new OEL for hydrazine based on Directive (EU) 2017/2398 as an additional exemption avenue
Figure 1 (exemption overview)	Revised to • reflect an additional use case, i.e. purification *to* hydrazine anhydrous in EEA – previously mentioned as a possible future use; • align with ECHA terminology ('mandatory precursor uses' → 'upstream life-cycle steps'); • clarify that loading of propellant is also performed on non-EEA launch sites; • update the exemption basis for the target application (hot firing in space vehicle) from 'article use' to 'substance use as fuel in closed systems' (REACH Art. 56(4)(d), 2nd alternative), taking into account the judgment of the CJEU of 10 September 2015 in case C-106/14 and update of the ECHA SiA Guidance to version 4 in June 2017; • Clarify that all hot firing in space vehicle takes place outside the EU/EEA territory / in space. Minor editorial changes were also made.
Figure 2 (overview of propellant-related use)	Revised in line with Figure 1 (see above)
Section 2. (Space programmes impacted)	Removed reference to Ariane 5: ECA, the only remaining operational version of Ariane 5 does not use hydrazine.
Section 2. and Annex 1.10.; Figure 1 and Figure 2 (hydrazine hydrate)	Clarified that purification of hydrazine hydrate to hydrazine anhydrous in EEA is now an actual use (previously not performed and only indicated as a future use in the initial position 2012)
Section 3.1.1. and Annex 2 (Hot firing in space vehicle as exempted substance use)	Updated the exemption basis and assessment for the target application (hot firing in space vehicle) from 'article use' to 'substance use as fuel in closed systems' (REACH Art. 56(4)(d), 2nd alternative), taking into account the judgment of the CJEU of 10 September 2015 in case C-106/14 and update of the ECHA SiA Guidance to version 4 in June 2017. Accordingly, the previous Section in the initial position 2012 titled "hot firing in space vehicle as exempted article us" has been removed and the text has been updated accordingly throughout the paper.

Section 3.1.2. (Use as fuels in closed systems, REACH Art. 56(4)(d))	Added reference in Section 3.1.2. to ECHA Q&A 1028, which confirms applicability of REACH Article 56(4)(d) to upstream life-cycle steps preceding the end use.
Section 3.2. (Uses occurring outside the EU/EEA territory / in space)	This sub-section has been added to clarify which uses are also considered to be outside the REACH territorial scope. The reference to specific cases (e.g. mission IXV is past) was removed due to redundancy. A reference to the French Space Act (L.O.S.) safety requirements applied has also been added. The corresponding text has been updated accordingly also in Section 2. and Annex 1.1.
Section 3.3. (SRD exemption for test uses, REACH Art. 3(23))	Added references in Section 3.3.1. to ECHA Q&As which confirm applicability of REACH Article 3(23) to analytical activities such as monitoring and quality control (Q&A 0585) and upstream life-cycle steps preceding the end use in SRD (Q&A 1030). Added reference in Section 3.3.2. to the interpretation of “controlled conditions” in ECHA SR&D Guidance, Version 2.1 (October 2017), confirming the interpretation suggested in the initial position 2012.
Section 3.5. (*new*)	Insertion of a reference to REACH Article 58(2) and the recent Directive (EU) 2017/2398 covering Hydrazine (new binding EU OEL) as an additional exemption avenue
Annex 1	Minor updates to align with core text / clarify in Annex 1.1.-1.3., 1.5. and 1.9.
Annex 2 (Classification of hot firing in space vehicles according to ECHA SiA Guidance (2017))	Updated the exemption basis and assessment for the target application (hot firing in space vehicle) from ‘article use’ to ‘substance use as fuel in closed systems’ (REACH Art. 56(4)(d), 2nd alternative), taking into account the judgment of the CJEU of 10 September 2015 in case C-106/14 and update of the ECHA SiA Guidance to version 4 in June 2017.
Annex 3 (*new*)	Added to reflect the extension of position to other liquid propellants MMH, NTO/MON-x and UDMH based on 2nd exemption study 2019
Annex 4 (*new*)	Added list of key acronyms in the revised position 2020
Annex 5 (*new*)	The present change history
Appendices 5-7	The names of the companies authoring the documents have been updated, where they have changed in the meantime. In Appendix 6 the reference to Ariane 5 has been removed, because Ariane 5 ECA, the only operational version of Ariane 5 remaining today, does not use hydrazine.