EXEMPTION DOSSIER REQUEST FROM THE REACH AUTHORISATION REQUIREMENT

REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS (REACH) EC/1907/2006

N,N-DIMETHYLFORMAMIDE – DMF (CAS # 68-12-2)

used for a glass coating process

PART 1: - Information on the specific use for which an exemption from the authorisation requirement is requested.	Submitted publicly
PART 2: - Glass coating process pictures. - Summary of the research performed by the company to substitute DMF.	Submitted confidentially

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Part 1 : Public submission

1. Executive Summary

N,N-Dimethylformamide (DMF), CAS # 68-12-2 has been included in the 5th prioritisation list for authorisation in the framework of the REACH Regulation.

The draft background document prepared for DMF by ECHA concludes that "*the uses as described in the registration dossiers entail potential for significant workers exposure at some stages of the industrial processes (…)".* Additionally, it concludes that "*there seems to be no specific Community legislation in force that would allow consideration of exemption(s) of (categories of) uses from the authorisation requirement on the basis of article 58(2) of the REACH Regulation*".

The company hereby provides comments on the draft background document prepared by ECHA in the context of the public consultation which closes on September 23rd , 2013.

DMF is used as part of a glass coating production process at only one of its sites located in Belgium. This use was registered by the company's suppliers during the registration process in 2010. To the best of the company's knowledge, this site is the sole glass coating producer using DMF in Europe. Therefore, the quantities of DMF involved for this use are limited (<500T/year) and concentrated at one geographic place which allows that risk management measures are consistently applied for this use which takes place during 100 days/year. Furthermore, the production process is unique and this specific glass coating process is patented.

DMF is needed in the formulation of a mixture which is further sprayed on glass to produce a metal oxide coating on the glass. The DMF contained in the mixture evaporates during the process and is not part of the final product. Thanks to its physico-chemical properties, this substance allows having a high degree of uniformity of thickness and composition of the coating on the glass surface. Additionally, the use of DMF allows the application of coatings on glass at very high temperatures without the risk of fire or explosion. Until today, there are no other alternative materials than using DMF for this specific use.

The company urges the Competent Authorities to consider an exemption from the proposed authorisation requirement for the specific use of DMF in a glass coating process on the basis of article 2(8) and 58(2) of the REACH Regulation, amongst other considerations which are all expressed below:

1. The site fulfills its obligations under REACH. The specific use of DMF was registered and covered by its suppliers in 2010.
2. DMF is a transported isolated intermediate which is exempted from Title VII (authorisation), under article 2(8) of REACH. DMF is manufactured at one site by its suppliers and consumed at the site for one glass coating process. The DMF contained in the mixture of metallic salts is transformed into other compounds during the spraying of the mixture on the glass. These latter compounds are not present in the final product (*i.e.*, glass). DMF thereby meets the definition of a transported isolated intermediate.

3. Different Community legislations that are properly transposed into Belgian legislation impose minimum requirements for the use of DMF. Under REACH article 58(2), *uses or categories of uses may be exempted from the authorisation requirement provided that there is an existing specific Community legislation that ensures a proper level of risk management for health and the environment.* These legislations include:

    - the Integrated Pollution Prevention Directive 96/61/EC (now Industrial Emissions Directive 2010/75/EU);
    - the Commission Directive 2009/161/EU and the Directive on chemical agents at work (98/24/EC);
    - the EU Directive on protecting the health and safety at work of pregnant women and workers who have recently given birth or who are breastfeeding (90/394/EEC) and the Council Directive on the measures to encourage improvements in the safety and health at work of pregnant workers and workers who recently given birth or are breastfeeding (92/85/EEC).

    These legislations were respectively transposed into Belgian legislation via:

    - the environmental permitting conditions of the site (*the site's permit imposes air emissions limits and a monitoring of the total organic compounds, including volatile organic compounds, and therefore the emissions related to the use of DMF are controlled*);
    - the modifications made in the Arrêté Royal (A.R.) of March 11, 2002 through the A.R. of May 20, 2011 (*the site developed a risk analysis linked to the use of dangerous chemicals used in the glass coating process. As a result, the adequate prevention measures in accordance with sections III and IV of this A.R. were implemented. Since the harmonized Occupational Exposure Limit (OEL) values for DMF were transposed in annex I of this A.R., occupational monitoring (on top of bio-monitoring) is performed according to the NBN EN 689 standard*). The transposed OEL values are the same than the REACH DNELs derived values (i.e., TWA: 15 mg/m³, STEL: 30 mg/m³ vs. $DNEL_{long\ term\ exposure}$: 15 mg/m³ and $DNEL_{acute\ exposure}$: 30 mg/m³) therefore, the transposed OEL meets the requirements of REACH in this relief;
    - the A.R. of May 2, 1995 (*the duration, the frequency and the exposure to DMF must be evaluated by the site in order to evaluate the risks of using of DMF for the workers. Bio-monitoring is performed annually at the end of the workers' shifts. The medical department of the site has at its disposal the list of dangerous chemicals used on site and their risks for the workers. As a result, this department follows closely the medical dossier of the workers performing tasks that involve these chemicals*).

4. The use of DMF is performed under strictly controlled conditions as per article 18(4) of REACH:

    - the substance is rigorously contained by technical means during its whole lifecycle,
    - procedural and control technologies are used in order to minimise the risk of emission and any resulting exposure,
    - only highly trained personnel is allowed to work with operations involving DMF,
    - special procedures for cleaning and maintenance works are implemented,
    - in cases of accident and where waste is generated, procedural and/or control technologies are used,
    - substance-handling procedures are well documented and strictly supervised by the site operator.

    The site regularly performs biomonitoring, environmental and occupational exposure campaigns in order to

verify that the workers are not exposed to DMF. The results of the monitoring shows that the levels of DMF exposure are close to zero or equal to zero. Additionally, DMF fully degrades into other compounds during the production process and therefore there is no emissions to which the workers or the environment could be exposed.

5. It would be disproportionate from an administrative and a financial standpoint to place the use DMF for the glass coating process in annex XIV. The substances produced during the glass coating manufacturing process are exempted from registration under REACH (REACH Regulation, annex V (3)), the substance glass itself used in the glass coating process is exempted from registration (REACH Regulation, annex V (11)[1]), consumers are not exposed to DMF as the final product placed on the market does not contain this substance. DMF degrades into other substances during the glass coating process and the use of DMF is performed under strictly controlled conditions. Additionally, the company tried to substitute DMF since 1996. The work to identify an alternative to DMF is still on-going outside the authorisation scope of REACH but so far, no adequate substitute has been found.

2. Introduction

The company produces, processes and distributes flat glass for the construction (external glazing and interior decorative glass), automotive (original and replacement glass) and solar sectors. The company has over 100 sites throughout Europe and employs 14,500 people.

Under the REACH Regulation EC1907/2006, the company is mainly a downstream user of substances and preparations. The company takes care that its suppliers are in compliance with REACH and that they have pre-registered, registered or will register their substances and cover its uses.

The company has a long-standing policy of avoiding the presence of dangerous substances in its products as much as possible, and that none of the substances identified as SVHC (Substances of Very High Concern) that may become subject to authorisation is present at concentrations of more than 0.1% by weight in its products.

Similarly, the company has a long-standing policy of avoiding the use of dangerous substances in its production processes. Nevertheless, when dangerous substances are used because there is no other possible safer substance alternative, the company implements the needed risk management measures to avoid emissions of the dangerous substances in the workplace and in the environment.

Dimethylformamide (DMF) has been included on the 5th prioritisation list for authorisation in the framework of the REACH Regulation. In this context, a public consultation period which will last 3 months has been launched. This period started on June 24th 2013 and will be finished on September 23rd 2013. ECHA will collect the comments and take into account the valid ones for updating the draft recommendation for inclusion in the authorisation list.

DMF is used in one of the company production sites located in Belgium. This site occupies 550 employees and produce several types of raw glass addressed to the automotive, building and solar sectors.

3. Use of DMF at the site

The site processes pyrolytic coating for certain types of glass and for some of the coatings, DMF has been used for more than 30 years.

To the best of the company knowledge, this site is the sole glass coating producer using DMF in Europe. The production process is unique and this specific glass coating process is patented.

The specific process performed at the site for forming a metal oxide coating is unique. A metallic coating is formed on a substrate which may be vitreous, partially vitreous or non-vitreous by applying to the substrate a solution of one or more metallic salts selected to the group of the acetates, halides and nitrates in an aprotic solution having a dielectric constant greater than 15 and a dipolar moment greater than 3D. The substrate and applied solution are then subjected to heat to convert in situ the metallic salt to form a coating comprising at least one metallic oxide.

The object of this invention was to provide a novel and improved method for producing metallic oxide coatings of uniform thickness and composition of various substrates. It was another object of the invention to provide a method whereby metallic oxide coatings having a high degree of uniformity can be formed on the surface at least partially vitreous surface, so that the method can be used for forming optical films on vitreous bodies or articles, for examples glazing sheets, windscreens, patterned glass and lenses for sunglasses. Additionally, the invention allows to provide a method whereby metallic oxide coatings can be produced with antistatic or electrically conductive properties.

The choice of the substance is crucial in order to obtain a coating uniformity. The use of DMF is particularly suitable for most of the metallic salts so that these compounds may be applied in relatively high concentrations, which means that the speed of application of the solution to a given zone of the surface of a substrate can be relatively low to produce a coating given thickness. DMF can also be used to apply coatings to substrates at very high temperatures without the risk of fire or explosion.

Consumers of such glass coated products are not exposed to DMF as DMF is not present in the product (DMF is fully transformed into other substances due to the high temperature used during the coated glass production chemical process).

4. Environmental, health and safety legal obligations at the site

4.1. REACH obligations

4.1.1. General exemptions

4.1.1.1. Surface glass treatment/coating exemption from registration under REACH

During the glass coating process, the substances produced by the company result “from a chemical reaction occurring upon end use of other substances, preparations or articles and which are not themselves manufactured, imported or placed on the market”. Therefore, these substances are exempt from REACH registration under annex V(3) of the REACH Regulation. Indeed, the substances produced during the site’s glass coating manufacturing process are the result of the chemical reaction occurring upon the end use of the starting substances which react on the surface of the glass.

4.1.1.2. Glass and registration exemption

Based on the nature of the substance glass and its specific generic inertness, the European Commission added glass to the list of substances exempted from the "obligation to register" (REACH Regulation, annex V (11)[1]). This exemption is limited to the compliance with the following requirements:

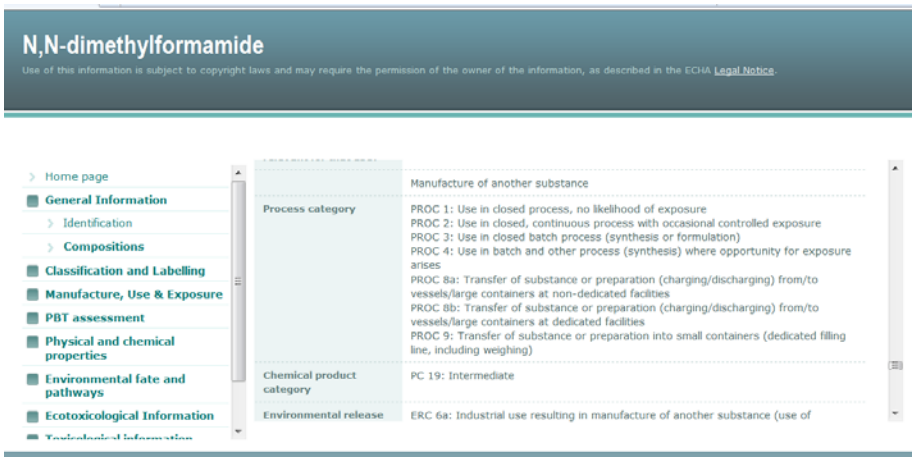
"The following substances unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC and provided that they do not contain constituents meeting the criteria as dangerous in accordance with Directive 67/548/EC present in concentrations above the lowest of the applicable concentration limits set out in Directive 1999/45/EC or concentration limit set out in annex 1 to Directive 67/548/EEC, unless conclusive scientific experimental data show that these constituents are not available throughout the life-cycle of the substance and those data have been ascertained to be adequate and reliable : Glass, ceramic frits".

Based on conclusive scientific data fulfilling the annex V(11) criteria, the glass itself, which is the basic constituent of the company’s products, is exempted from registration.

4.1.2. Use registration

The company made its use known to its DMF suppliers in July 2010. This use has been included in their registration dossier (see screenshot from the ECHA website). This use has further been communicated via their Safety Data Sheet and the exposure scenario was checked against the local operating conditions and RMMs. The site’s DMF use is covered by the supplied SDS (see DMF Safety Data Sheet in annex 1).

[1] Commission Regulation (EC) No 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards to Annexes IV and V.



4.1.3. Transported isolated intermediate status of the DMF used at the site

DMF is manufactured at one site by the company's suppliers and consumed/used at the site for one glass coating process. The DMF contained in the mixture of metallic salts is transformed into other compounds during the spraying of the mixture on the glass. These compounds are not present in the final product (*i.e.*, glass). DMF thereby meets the definition of a transported isolated intermediate in this case.

Article 3(15) of REACH provides that an "intermediate" is *"a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis)".* From this definition, the following conclusions can be drawn: (i) an intermediate is a substance, (ii) for such a substance to qualify as an intermediate, the key element is the intention to transform it into another substance through chemical processing, and (iii) the manufacture and the use of that substance are followed by its transformation into another substance through chemical processing.

Therefore, given article 3(15) of REACH and its use at the site, DMF is considered as a transported isolated intermediate which is exempted from Title VII (authorisation), under article 2(8) of REACH.

4.2. Community legislations imposing minimum requirements for the use of DMF

Several Community legislations impose minimum requirements relating to the protection of human health or the environment for the use of DMF so that its use is properly controlled at the site from its delivery stage until the substance degradation in the chemical process. Under REACH article 58(2), uses or categories of uses may be exempted from the authorisation requirement provided that there is an existing specific Community legislation that ensures a proper level of risk management for health and the environment. This section describes the range of applicable Belgian national regulations that transposed the Community legislations applicable to the site.

4.2.1. Environmental legislation

COMMUNITY LEGISLATION/STANDARD	APPLICATION AT THE SITE	REFERENCES
Directive 2008/1/EC concerning integrated pollution prevention and control	The site operates under the IPPC Directive (96/61/EC) which ensures a high level of protection of the environment. The Directive is transposed in the environmental permit of the site. The permit conditions of the site are therefore based on the Best Available Technologies for the manufacture of glass and the site is subject to regular Authorities environmental inspections using risk-based criteria. The permit imposes air emissions limits and a monitoring of the total organic compounds (including volatile organic compounds) and therefore the emissions related to the use of DMF are controlled.	Environmental permit reference: PE/PU/AB/MP/2006
ISO 14001	The site's operations are certified ISO 14001 which maintains a high level of excellence for the environmental risk management.	ISO 14001 Certificate see annex 2

4.2.2. Human health legislation

The use of DMF in industrial settings, more specifically, its "occupational use" or its "contact at the workplace", is regulated by different European Community legislations.

COMMUNITY LEGISLATION/STANDARD	APPLICATION AT THE SITE
Commission Directive 2009/161/EU establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC **Directive on chemical agents at work (98/24/EC)**	DMF was included in the third list of Indicative Occupational Exposure Limits Values (IOELVs) set up by Commission Directive 2009/161/EU (17.12.2009). Member States were subsequently required to establish a national occupational exposure limit value, taking into account the Community limit value of DMF by 18 December 2011. Belgium transposed the Community limit values of DMF into the A.R of March 11, 2002 concerning the protection of health and security of workers against the chemical agents risk at the workplace through the **A.R of May 20, 2011** (see annex 3). The limit values for DMF are included in annex I of this A.R. (TWA: 15 mg/m³, STEL: 30 mg/m³). The transposed OEL values are the same than the REACH DNELs derived values (i.e., TWA: 15 mg/m³, STEL: 30 mg/m³ vs. $DNEL_{long\ term\ exposure}$: 15 mg/m³ and $DNEL_{acute\ exposure}$: 30 mg/m³) therefore, the transposed OEL meets the requirements of REACH in this relief. Therefore, the Directive 2009/161/EU properly addresses the occupational use of DMF and health risk in connection with its use and the site must comply with the occupational limits. The IOELVs are adopted as implementing measures within the framework of the Directive on chemical agents at work (98/24/EC). This Directive defines "activity involving chemical agents" in article 2(c) as "any work in which

COMMUNITY LEGISLATION/STANDARD	APPLICATION AT THE SITE
	chemical agents are used, or are intended to be used, in any process, including production, handling, storage, transport, or disposal and treatment, or which results from such work". Therefore, read in combination, the IOELVs Directive and the chemical agents at work Directive addresses the "contact at the workplace" category for the specific use of the site. The use and risk management of DMF at the site are controlled by the **A.R of May 20, 2011**. In accordance with article 9 of this A.R, the site developed a risk analysis linked to the use of dangerous chemicals used in the glass coating process. the site implemented the adequate prevention measures in accordance with sections III and IV of this A.R. (see section 5.4). Since limit values for DMF were transposed in annex I of this A.R., the site performs occupational monitoring (on top of bio-monitoring) according to the NBN EN 689 standard. The occupational monitoring is done in compliance with section X of this A.R. The results of the monitoring have shown that the risk is limited as the level of exposures to DMF are low or equal to zero (see section 5.5).
EU Directive on protecting the health and safety at work of pregnant women and workers who have recently given birth or who are breastfeeding (90/394/EEC) **Council Directive on the measures to encourage improvements in the safety and health at work of pregnant workers and workers who recently given birth or are breastfeeding (92/85/EEC)**	DMF is classified and labeled as a reprotoxic Cat. 1B under the CLP Regulation (1272/2008) and is included in annex VI, part 3 (index number 616-001-00-X) table 3.1 (list of harmonised classification and labeling of hazardous substances). Therefore, the management of this substance in industrial settings is covered by the EU Directive on protecting the health and safety at work of pregnant women and workers who have recently given birth or who are breastfeeding (90/394/EEC) and Council Directive 92/85/EEC (measures to encourage improvements in the safety and health at work of pregnant workers and workers who recently given birth or are breastfeeding). Amongst others, this Directive establishes guidelines for assessing the risks related to chemicals, and provides minimum requirements for the control of the risks of use of chemicals. The Council Directive 92/85/EEC was transposed in the Belgian national legislation via the **A.R. of May 2 1995** concerning the maternity protection (see annex 4). DMF is included in Annex II of the A.R referring to the list of chemical agents that are forbidden under the specific measures of article 7(2) of this A.R. The use and risk management of DMF at the site is controlled by the A.R of May 2, 1995 concerning the maternity protection. The risks for pregnant workers and workers who have recently given birth or are breastfeeding are controlled. When a risk relevant to the use of DMF is defined in accordance to article 41 of the work regulation of March 16, 1971, the site takes the appropriate measures as per article 42(1) of the same regulation. The duration, the frequency and the exposure to DMF must be evaluated by the site in order to evaluate the risks of using of DMF for the workers. Bio-monitoring is performed annually at the end of the workers' shifts, occupational exposure monitoring is as well performed (see sections 5.5 and 5.6 of this report). The medical department of the site has at its disposal the list of dangerous chemicals used on site and their risks for the workers. As a result, this department follows closely the medical dossier of the workers performing tasks that involve these chemicals.
OHSAS 18001	The site's operations are certified OHSAS18001 which maintains a high level of excellence for the health & safety risk management at the workplace (see certificate

COMMUNITY LEGISLATION/STANDARD	APPLICATION AT THE SITE
	in annex 5).

4.3. The use of DMF is performed under strictly controlled conditions

The use of DMF for a glass coating process at the site fits with the requirements of Strictly Control Conditions (SCC) that are listed in article 18(4) of REACH:

REACH SCC CRITERIA	APPLICATION AT THE SITE	REFERENCE
a) **the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage**	DMF is rigorously contained from its delivery stage at the site until its transformation into other substances during the chemical process at the site.	See section 5
b) **procedural and control technologies shall be used that minimise emission and any resulting exposure**	Procedures are in place and the workplace is equipped in order to limit emissions and exposure to DMF according to section III and IV of the A.R of May 20, 2011.	See section 5
c) **only properly trained and authorised personnel handle the substance**	The personnel of the site is trained in order to safely handle dangerous substances. This must be done according to section VI of the A.R of May 20, 2011.	See organisational measures section 5.8 : trainings
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**	Special procedures are in place when maintenance and cleaning need to be carried out at workplace involving DMF.	See organisational measures section 5.8: Procedure: Protective Personal Equipment to be worn during the cleaning and maintenance of operations involving DMF
e) **in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures**	Procedures are in place and control technologies have been implemented in order to minimise the risk of emission of DMF in case of accident and where waste is generated. There is no release/emissions of DMF in the environment under normal and foreseeable use conditions at the site. Therefore, its use is well controlled from an environmental standpoint.	See section 5 and organisational measure section 5.8: Procedure: measures to be taken to minimise the emissions of DMF in case of accident and where waste is generated.
f) **substance-handling procedures are well documented and strictly supervised by the site operator.**	The substance-handling procedures are well documented and supervised by the site operator and readily available in case of audit.	substance-handling procedures readily available in case of audit

4.3.1. Proportionality principle

Article 58(2) of the REACH Regulation states that *"Uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community 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. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form".*

Although grounds of human health protection may justify more control on the use of DMF within the context of the REACH Regulation, measures must comply with the principle of proportionality. They must be confined to what is actually necessary to ensure the safeguarding of public health and they may not be excessively burdensome in relation to the objective pursued.

The specific usage of the DMF at the site involves:

- that the substances produced during the glass coating manufacturing process are exempted from registration under REACH (see section 4.1.1.1);
- that the substance glass itself produced at the site and used in the glass coating process is exempted from registration (see section 4.1.1.2);
- that there are strict Community legislations that properly address the risks management linked to the use of DMF and its control at the site (see section 4.1.2);
- that the substance is a transported isolated intermediate (which is exempted from the authorisation scope of REACH) which fully evaporates and decomposes into other substances during the production process (4.1.3);
- that operations are performed under strictly controlled conditions in order to properly manage the risks incurred with its use (see section 4.1.5).

Therefore, as neither the glass substrate nor the substances produced during the glass coating process are subject to a registration under REACH, that there are strict Community legislations that apply to the use of DMF which is a transported isolated intermediate used under strictly controlled conditions, it would be disproportionate to include this DMF specific use in annex XIV.

Additionally, consumers are not exposed to DMF as the final product placed on the market does not contain this substance (tests have been performed on the final product by an external laboratory in order to detect if DMF is present in the product, see annex 6), it would be disproportionate from an administrative and financial standpoint to place DMF in annex XIV of REACH for the site's specific use. Additionally, the company tried to substitute DMF since 1996 given its toxicity profile. The work to identify an alternative to DMF is still on-going outside the authorisation scope of REACH.

5. Process steps involving the use of DMF in the production of glass coating

5.1. Introduction

The process steps involving the use of DMF in a mixture for the production of a glass coating is described in this section together with the implemented controls to manage the risk of its use.

Section 5.2 describes the process flow and provide explanations for each process step.

Section 5.3 provides pictures for each process step description. This section is submitted confidentially in Part 2 of the dossier because the pictures are directly linked to the production process and to the engineering know-how of the company. If this information is disclosed, it would be commercially harmful to the company.

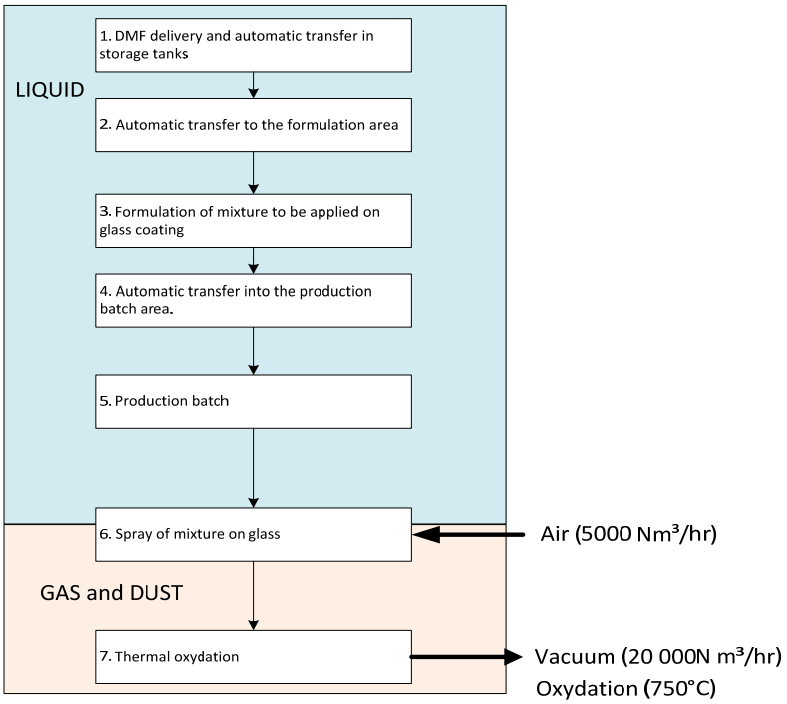
Section 5.4 depicts the overview of the Risk Management Measures - RMM (collective measures and Personal Protective Equipment – PPE measures) by process step for Human health.

The occupational monitoring and biomonitoring information done at the site are respectively presented in section 5.5 and 5.6 while the environmental monitoring is presented in section 5.7.

Section 5.8 refers to other organisational measures that are taken on the site in order to strictly control the risks.

5.2. Process flow and explanations

The flowchart below shows the different step processes involving DMF use for the glass coating process. The physical state of DMF is as well described in the flowchart.



PROCESS STEP	PROC	DESCRIPTION
1. DMF delivery and	PROC2	The DMF solution (99.9%) is delivered at the site directly by tankers (see DMF Safety Data Sheet in annex 1).

PROCESS STEP	PROC	DESCRIPTION
automatic transfer in storage tanks		During the transfer operation of the solution to the storage area, the tanker is positioned on top of a retention basin (see picture 1). In case of accidental spill during this operation, the solution flows in the retention basin (capacity 30 m³) and is further collected by pumping the solution into IBCs. The DMF solution is directly transferred in the tanks of the warehouse via pipes that are connected to the storage tanks and to the tanker. Picture 2 shows the pipe connection system used during the transfer of DMF to the warehouse. The operator must wear personal protective equipment during the transfer operation of the substance: chemical gloves, respiratory protection with cartridges against organic vapors (ABEK type). Picture 3 shows the workplace sign advertising the hazard statements for DMF and the required PPE to be worn. The duration and frequency of this operation for the protected operator is 1 day/month, 1 min/day. The DMF delivery and the automatic transfer of the solution through the piping system to the two storage tanks via a pump is therefore undertaken under closed and strictly controlled conditions. There is no possible exposure during this operation (see picture 4). The storage tanks are located in a warehouse dedicated to the DMF storage only. Both tanks are positioned at 2m height on a retention basin (see picture 5). The access to this warehouse is only authorised during the transfer operation and, exceptionally, to a limited number of persons. There are retention basins on the walk side of the storage area (see picture 6). There can be some DMF waste generated at the mouth of the pipe that arrives at the warehouse during the maintenance operation of the pump. In such case, the waste are handled with the same PPE than the ones required during the transfer operation. The solution is placed in a small plastic container of 0,5L and evacuated in the waste storage area and taken away via an external waste processor firm (see picture 7). Stage 1 operations are conducted at ambient temperature.
2. Automatic transfer to the formulation area	PROC2	When a production of coated glass is foreseen, the DMF contained in the tanks is then routed to the formulation area via the automatic piping system (see picture 8).
3. Formulation of mixture to be applied on glass coating	PROC3	The piping system delivers the DMF in a hot water bath tank of 400L where the temperature of the liquid is gradually increased up to 45°C (see picture 9). If the temperature of the liquid reached 50°C, the heating system automatically stops as the DMF flashpoint is 65°C. When the liquid has achieved the desired temperature, it is routed via pipes into two bigger tanks where the formulation takes place (see picture 10). The other compounds of the mixture are then transferred via an individual piping system into theses tanks. These tanks, which keep the mixture temperature at 45°C, are closed and there is a LEV system sized for the

PROCESS STEP	PROC	DESCRIPTION
		whole formulation room (efficiency: 4000 Nm³/hr). Within the formulation area, there is a separate and enclosed control room where the operator monitors the formulation stage. As the formulation system is fully automatised, it is estimated that the operator works only for 15 min per week in the control room and in the whole formulation area. In addition, there is a LEV system in the enclosed control room (see picture 11). The concentration of DMF in the mixture is 93% v/v. There could be some waste during the production process that will be transferred into a labelled IBC (see picture 12). The IBC is further evacuated by an external firm. Stage 3 operations are conducted under strictly controlled conditions (automated, closed system and LEV).
4. Automatic transfer into the production batch	PROC1	The mixture containing DMF is transferred via the closed piping system to the production batch rooms. There is no possibility of exposure for the operators at this stage (see picture 13).
5. Production batch	PROC1 Filter maintenance (PROC2)	The piping system splits into two in order to distribute the mixture in the two enclosed production batch rooms (see picture 14). The production batch rooms are equipped with a LEV system (efficiency: 2000 Nm³/hr) and the operations in both rooms are controlled remotely so there is no contact of the operator with the solution (see picture 15). The operator will only enter the room 3 to 4 times for a total of 5 min to verify that the remote automatic start worked well when there is a production need. In the production batch area of the first line, there is a retention basin (see picture 16). From time to time, the piping system that routes the DMF mixture is cleaned between the production batch and the mixture formulation area. The pipe is rinsed by injection of the pure DMF solution. The pure DMF solution arrives by pipe directly from a connection in the formulation room piping system (see picture 17). The temperature of the mixture which arrives in the autoclaves is 45°C. The pressure is raised in the autoclaves. The operator enters the room for cleaning and maintenance when the filters have to be discarded (see picture 18). PPE (ABEK gas filter, chemical gloves) must be worn during this operation. The filters containing mixture residues are discarded as an hazardous waste and their removal from the site is outsourced by an external waste processor firm. As the production batch area is fully automatised, the operator works only for 10 min per month in the autoclave room. Similarly to the different process steps, stage 5 operations are conducted under strictly controlled conditions (automated, closed system, retention

PROCESS STEP	PROC	DESCRIPTION
		basin in one room and LEV, cleaning and maintenance procedures). When the mixture has achieved the desired temperature, it is then transferred via the closed piping system to the coated glass production line.
6. Spray of mixture on glass	PROC7	The piping system containing the mixture connects automatically with the on-line spraying system (see picture 19) installed on top of the glass coating production line (see picture 20). The spraying machine is automatised and the solution is pulverised on line in a move from left to right of the float (speed of on-line spray: 5m/sec). It is controlled by distance by the operators that are located in an enclosed control room away from the DMF mixture exposure zone. The frequency and duration of exposure of the operators in this area is 1-2 hrs/day, 100 days/year. The temperature on-line during the spraying process varies between 200-250°C. At this temperature, the DMF contained in the mixture vaporises, degrades and is taken away by the air flow spread on line at 5000 Nm^3/hr to the mouth of the thermal oxidation installation. The industrial spraying is performed in an enclosed system which is depressurized. The mixture's vapors can therefore not escape the production process. At the mouth of the thermal oxidation installation, the atmosphere is aspired (20 000 Nm^3/hr - an air flow meter connected to the control room is installed at the level of the LEV) which immediately drives the DMF vapor in the air treatment system (see picture 21). Therefore, the final coated glass product does not contain DMF (see analytical report of the final product in annex 6).
7. Thermal oxydation	PROC1	The temperature is raised to 750°C in the thermal oxidation process. At this temperature, the DMF contained in the mixture breakdowns into other degradation products. The first gas burner is located at height to avoid that the DMF burns (see picture 22). This air treatment process will destroy any remaining contaminants when passing through the incineration stage (see picture 23). After the incineration stage of the dusts are collected in the installation (see picture 24) and further transferred into IBCs (see picture 25). As a result, DMF is not emitted in the air and the dust collected at the end of the thermal oxidation treatment installation does not contain DMF (see section 5.7 on environmental monitoring).

5.3. Process pictures

This section is submitted confidentially in Part 2 of the dossier because the pictures are directly linked to the production process and to the engineering know-how of the company. If this information is disclosed, it would be commercially harmful to the company.

Detailed overview of the risk management measures by process step for Human health

PROCESS STEP	PROC	DESCRIPTION TECHNICAL MEASURES	DESCRIPTION PERSONAL PROTECTIVE EQUIPMENT
1. DMF delivery and automatic transfer in storage tanks	PROC2	Closed	• Long leave vest • Helmet • Gas filter mask (type ABEK) • Goggles (type EN166 – EN168) • Gloves (Chemical gloves – EN374)
2. Automatic transfer to the formulation area	PROC2	Closed + Automated	• Not applicable • Helmet • Goggles (type EN166 – EN168)
3. Formulation of mixture to be applied on glass coating	PROC3	Closed + Automated + LEV (4000 Nm3/h)	• Long leave vest • Helmet • Goggles (type EN166 – EN168) • Gloves (Chemical gloves – EN374)
4. Automatic transfer into the production batch	PROC1	Closed + Automated	• Not applicable • Helmet • Goggles (type EN166 – EN168)
5. Production batch	PROC1 Filter (PROC2)	Closed + Automated + LEV (2000 Nm3/h)	• Long leave vest • Helmet • Gas filter mask (type ABEK) • Goggles (type EN166 – EN168) • Gloves (Chemical gloves – EN374)
6. Spray of mixture on glass	PROC7	Closed + Automated + LEV (20000 Nm3/h)	When working in the near surrounding of the production line of the coated glass: • Long leave vest • Helmet • Goggles (type EN166 – EN168) • Gloves (Chemical gloves – EN374)
7. Thermal oxydation	PROC1	Closed + Automated + Depressurisation (20 000 Nm3/h)	When working in the near surrounding of the installation: • Long leave vest • Helmet • Goggles (type EN166 – EN168)

5.4. Occupational exposure monitoring

Occupational monitoring at the site is essential to ensure continued protection of employees. Occupational monitoring is therefore an integral part of the production process.

Over the years, the site monitored the occupational exposure linked to Volatile Organic Compounds potential emissions of the glass coating production process. The last DMF monitoring campaign was undertaken by an external Laboratory (Certech) which is accredited by the Walloon Region for measurements on the air quality and odor.

The measures show that the DMF levels are low or close to zero at all the different sampling locations. Static and personal monitoring were performed while the glass coating process was used. The sampling strategy followed the EN689 and the exposure was compared with the limit value of 15 mg/m³ (TWA).

The stationary sampling was performed for the following step processes:

- Warehouse area for the DMF tanks
- Formulation area
- Autoclave/production batch room
- Production line walkway
- Control room for the glass coating line and for the oven

Conclusion: the exposure levels are low or close to zero. The risk to exceed the limit value is low (less than 1 working day out of 1000).

The personal sampling was undertaken on 6 different operators:

- 2 coating operators and 1 coating foreman
- 1 float operator, 1 hot glass foreman, 1 hot glass multi-task worker

Conclusion: the samples collected on operators do not exceed the TWA. In general, exposure levels are low or close to zero.

The report of this analysis can be found in annex 7.

5.5. Biomonitoring

Biomonitoring is performed in compliance with the requirements of article 40 (section IX) of the A.R March 11 2002. Annex IV of this A.R provides the list of the techniques to be used together with the minimum frequency for the substances. Based on annex IV, the monitoring of N-méthylformamide (NMF) in urine shall be performed on an annual basis the operators exposed to DMF. The examination of DMF in urine is performed on an annual basis at the site for the operators who typically works at the production line where DMF is used. Even when the glass coating production process is not operating and that the workers are occupied in other areas of the site, biomonitoring can still be performed on their urine in order to secure a good medical follow-up.

The urine samples are taken at the end of the shift and further analysed by an external laboratory (UCL, Louvain Center for Toxicology and Applied Pharmacology, Belgium). The limit taken into consideration is 30mg/g of creatinine (based on the ACGIH BEI: 15 mg/l at the end of the shift). Based on various reports, the

correlation between the occupational exposure of DMF and the urinary concentrations of the NMF are good in general (a list of studies used to derive this value will be made available on demand).

A biological monitoring campaign was undertaken by the Louvain Center for Toxicology and Applied Pharmacology at the same time than the DMF occupational monitoring campaign during the glass coating production process described in section 5.5. Three urine samples were taken on the same workers than the one selected for the occupational monitoring at the beginning, in the middle and in the end of their shift.

The urine sampling was collected from the same 6 different operators:

- 2 coating operators and 1 coating foreman
- 1 float operator, 1 hot glass foreman, 1 hot glass multi-task worker

Conclusion: the NMF amounts present in the urine was analysed and shows that the results are below the quantification limit. The report of this analysis can be found in annex 8.

The table below shows the biomonitoring in urine performed between 2006 and 2012 at the site as an example (note: biomonitoring in urine has been performed since the beginning of the glass coating operations).

Year	Number of operators	Number of samples With and without the DMF use	average [N-Méthylformamide] mg/g of creatinine	Standard deviation	Tolerated value for the exposed workers [N-Méthylformamide] mg/g of creatinine
2006	30	55	0,038	0,162	30
2007	37	69	0	0	30
2008	38	78	0	0	30
2009	21	31	0,055	0,305	30
2010	22	25	0	0	30
2011	31	45	0,04	0,268	30
2012	17	18	0	0	30

Conclusion: the average concentration equals to zero, with some values higher than zero mg/g of creatinine but always well below the limit (30 mg/g creatinine).

5.6. Environmental Monitoring

Environmental monitoring on the VOC emissions of the glass coating lines are regularly made to control the performance of the air pollution control installation at the site.

The monitoring has shown that the gas composition is stable in time. The installation performs well for the reduction of VOC (VOC ≤ 8 mg C/Nm³). Overall, the abatement efficiency is higher than 99% for this pollutant and fully comply with the standard limit of 50 mg/Nm³.

5.7. Organisational mesures

In order to comply with its legal obligations and ensure a safe use of DMF, the site implemented different organisational measures. These measures are described below.

- Risk analysis: for the use of dangerous chemicals used in the glass coating process.
- Trainings: an induction on how to work with dangerous chemicals is made for each new comer and operator newly affected operations to these type of operations. Regularly, trainings on how to work with dangerous chemicals products are given/repeated to all operators.
- Procedure: PPE to be worn during the cleaning and maintenance of operations involving N,N-dimethylformamide – DMF (CAS # 68-12-2).
- Procedure: measures to be taken to minimise the emissions of DMF in case of accident and where waste is generated.
- Procedure: N,N-dimethylformamide – DMF (CAS # 68-12-2) substance handling.

6. Analysis of alternatives

The company has a longstanding environmental policy in order to avoid the use of hazardous substances in the workplace. When the development of a new process or new product involves the use of a hazardous substance, a specific procedure is immediately put in place. The objective of the procedure is to evaluate the hazardous material that is intended to be used in order to determine if it is allowed to become part of a new product or production process. During this evaluation, safer alternatives are also explored.

The company tried to substitute DMF since 1996 given its toxicity profile. The work to identify an alternative is still on-going and the section **submitted confidentially in Part 2** presents the main conclusions and information that are currently available at the time of submission of this report.

At present, the company did not yet identify an alternative product which satisfies both the specific physico-chemical requirements and a safe toxicological and environmental profile. The company works with its suppliers in order to find a substitute to DMF. This collaboration is part of the company internal R&D program called *'DMF substitution in the glass coating metallic solution'*. This program involves significant R&D efforts under which there is not yet a defined timeline for the completion of the DMF substitution.

Much of the information related to the research for alternatives to DMF in the glass coating production process contains Intellectual Property and must not be made publicly available. The confidential **submission in Part 2** details the critical properties and quality criteria providing key process parameters.

The alternative substance must not meet the criteria of article 57 of the REACH Regulation. Therefore, both NMP and DMAC were excluded from the panel of options available and further testing is not foreseen.

Annex 1

An extract of the SDS of the DMF supplied to the site can be found below in its French version. The operational conditions and risk management included in the exposure scenario that apply at the site are presented in the scenario DMF used as an intermediate (i.e., exposure scenario 2).

2. Titre abrégé du scénario d'exposition
Utilisation en tant qu'intermédiaire
SU3; SU9; ERC6a; PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC9; PC19

Contrôle de l'exposition et mesures de gestion des risques

Scénario d'exposition contributeur	
Descripteur des utilisations couvertes	ERC6a: Utilisation industrielle ayant pour résultat la fabrication d'une autre substance (utilisation d'intermédiaires) Aucun danger pour l'environnement n'ayant été identifié, il n'a pas été réalisé d'évaluation de l'exposition de l'environnement ni de caractérisation des risques.

Annex 2

Plant's ISO 14 001 certificate.

ISO 14001

Annex 3

Arrêté royal du 11 mars 2002 relatif à la protection de la santé et de la sécurité des travailleurs contre les risques liés à des agents chimiques sur le lieu de travail modifié par l'arrêté royal du 20 mai 2011 (M.B. 30/6/2011; erratum: M.B. 30.11.2011) [Transposition en droit belge de la directive européenne 2009/161/UE de la Commission du 17 décembre 2009 établissant une troisième liste de valeurs limites indicatives d'exposition professionnelle en application de la directive 98/24/CE du Conseil et portant modification de la directive 2000/39/CE de la Commission].

AR 11-03-2002F
agents chimiques (ave

Annex 4

Arrêté royal du 2 mai 1995 concernant la protection de la maternité (M.B. 18.5.1995; errata: M.B. 12.10.1995).

Arrêté royal du 2 mai
1995 concernant la pr

Annex 5

Plant's OHSAS 18 001 certificate.

OHSAS 18001

Annex 6

The analytical test report on the potential detection in the final glass coated product placed on the market can be found below. The test was undertaken by an external laboratory (SGS Belgium NV in Antwerp). The results show that the DMF concentration is below the reporting limit.

DMF-SGS-Test results

Annex 7

Analysis of Dimethylformamide in the workplace environment.

S494-13-486-english

Annex 8

Biological monitoring results performed at the site

Biological monitoring urine samples 2013M