Fédération de la Plasturgie comments on ECHA's ADCA Online Questionnaire

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“La Fédération de la Plasturgie” is the association of the French Plastics Converters based in Levallois-Perret, close to Paris, representing Downstream Users according to REACH.

“La Fédération de la Plasturgie” represents around 3,500 companies for a turnover of around 30 billion euros in 2011.

We are member of EuPC, the European umbrella association of Plastics Converters, is the leading EU-level Trade Association, based in Brussels. Its powerful European Plastics Network exists to support the beneficial use of plastics worldwide, especially providing plastics converting companies with a voice in European legislation.

EuPC now totals about 51 European Plastics Converting national and European industry associations; it represents around 50,000 companies, producing over 45 million tons of plastic products every year.

The European plastics industry makes a significant contribution to the welfare in Europe by enabling innovation, creating quality of life to citizens and facilitating resource efficiency and climate protection. More than 1.6 million people are working in about 50,000 companies (mainly small and medium-sized companies in the converting sector) to create a turnover in excess of 280 billion € per year.

After ECHA made a draft suggestion for diazene-1,2-dicarboxamide (C,C`-azodi(formamide)) EC Number: 204-650-8, CAS Number: 123-77-3, hereinafter

referred to as ADCA – for inclusion in the authorisation list in annex XIV of REACH with priority, EuPC created an ADCA Expert Group consisting of EuPC member companies which are using ADCA to manufacture some of their products, hereinafter referred to as EuPC. ADCA is a key chemical in the foaming of polymers. Its use is affecting almost 3.4 million tonnes of processed plastics products, hence an important substance for the plastics converters. In July EuPC started an enquiry by means of a questionnaire in order to provide an accurate input for the consultation. The questionnaire dealt with questions like market sectors involved with ADCA, the physical form in which ADCA is used, the different kind of polymers in which ADCA is used, in which different converting processes ADCA is used, final articles ADCA is converted to, level of exposure to ADCA, economic and environmental benefits of ADCA, workability of alternatives, impact of alternatives etc. EUPC members filled out the questionnaire individually on their own judgement. The EUPC consultation input is an aggregated observation of the received answers.

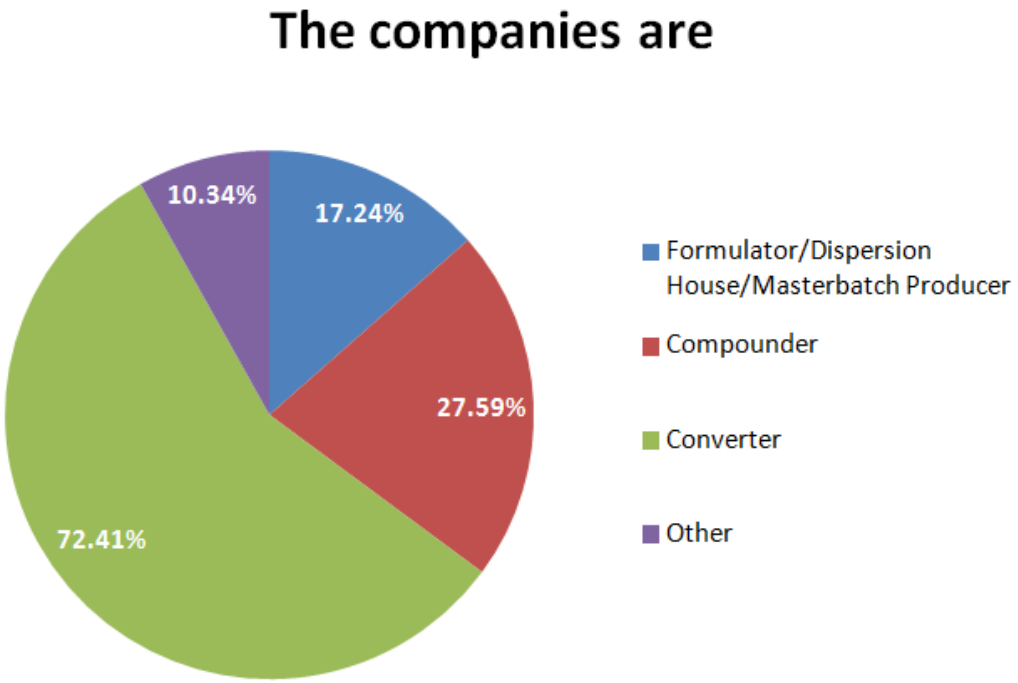
For the rest of the document, as a EuPC member company, “La Fédération de la Plasturgie”, fully supports the statement given by EuPC :

III (1) General Comments

Sectors, Converting Processes and End Applications

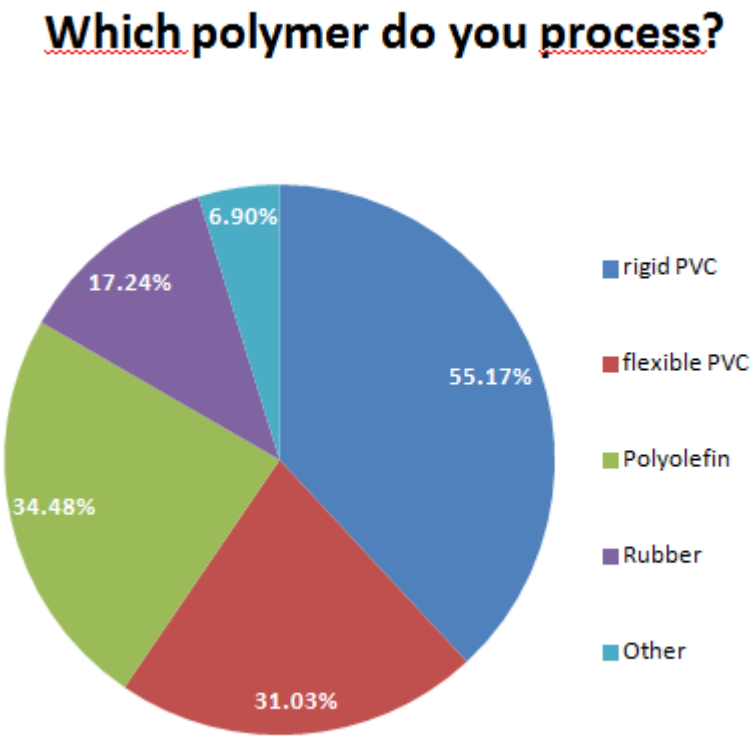
ADCA is primarily used as a blowing agent in the natural/synthetic rubber and plastics industries. It is used in the expansion of a wide range of polymers including PVC, polyolefins (PE, PO, TPO), PS, HIPS, TPU, EVA, and EPDM. ADCA is decomposed by heating to generate nitrogen gas, carbon dioxide gas, carbon monoxide gas, ammonium gas, or sometimes hydrogen gas etc. inside the base, and build up a cellular structure.

EuPC members are using ADCA in the following downstream sectors:



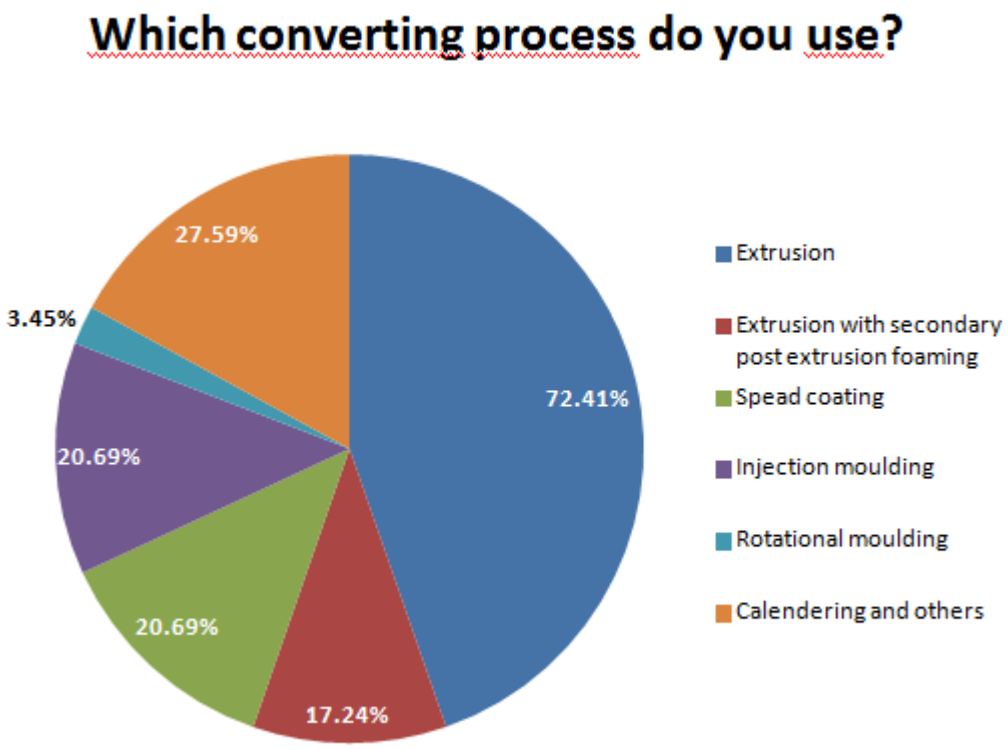
The total is more than 100 %. The reason for this is that some companies cover two or more sectors.

ADCA is used by EuPC for the expansion of polymers with the following distribution :



In this case, too, the total is more than 100 % because some companies use two or more polymers.

Plastics converters are using ADCA in a wide range of converting processes. The distribution is the following:



In this case, too, the total is more than 100 % because some companies have different production processes

ADCA is used in many different end applications. The most important are:

CONSUMER PRODUCTS

11.9 % household (e.g. hoses, bath and shower mats, table protection)
8.5 % sport, leisure and physiotherapeutic articles (e.g. shoe soles, gymnastic mats, table tennis bat coverings, canoes)
6.7 % packaging

CONSTRUCTION PRODUCTS

38.9 % construction products (e.g. cold water, hot water, sewage pipes, profiles, vinyl flooring, vinyl wall covering, thermal insulation)
5.1 % advertising (e.g. display products in building advertisement)
6.7 % others (e.g. cable and wire isolation, tarpaulins)

AUTOMOTIVE PRODUCTS

3.9 % safety (e.g. crash protection)
6.3 % cushioning, vibration and sound reduction, corrosion protection
8.0 % artificial leather, sealants
10.8 % others

III (2) COMMENTS ON THE RECOMMENDATION TO INCLUDE THE SUBSTANCE IN ANNEX XIV

ADCA DOES NOT FULFIL THE CRITERIA OF AN EQUIVALENT LEVEL OF CONCERN SUBSTANCE ACCORDING TO ART. 57 f REACH

ADCA does not fulfil the criteria of an equivalent level of concern substance according to Art 57 f REACH and thus should not be included in annex XIV

ECHA regarded ADCA as a substance of equivalent level of concern having probable serious effects to human health in the sense of Art. 57, f Regulation EC No 1907/2006, hereinafter referred to as REACH. Therefore, ECHA decided to include ADCA in the Candidate List for authorisation on 19 December 2012 (Decision ED/169/2012).

This decision was wrong. ADCA should have never been included in the Candidate List and should never appear in the future on the Authorisation List, annex XIV REACH.

The argumentation of ECHA for the classification of ADCA as an equivalent level of concern substance (Art. 57 f REACH) is mainly based on its properties as a respiratory sensitiser. ADCA is classified as Resp. Sens. 1 (H334: “May cause allergy or asthma symptoms or breathing difficulties if inhaled”) according to Regulation EC No 1272/2008, Annex VI, Table 3.1 (the list of harmonised classification and labelling of hazardous substances).

The fact that ADCA has the above-mentioned harmonised EU classification is not questioned.

EuPC strongly opposes the qualification of ADCA as an equivalent level of concern substance.

The classification as a respiratory sensitiser does not automatically result in the categorisation as an equivalent level of concern substance. EuPC already argued in this direction in the first consultation (inclusion of ADCA in the Candidate List).

Again: A substance has Art. 57 f REACH properties, when there is a scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern like a CMR, PBT or vPvB substance.

Equivalent level of concern is given when the following prerequisites have been fulfilled:

- Severity of health effects and
- Irreversibility and
- No safe concentration and
- Delay of health effects
- Societal concern and impairment of quality of life and

ADCA does not meet these prerequisites – apart from the fact that so far, there is no "non-safe concentration". The annex XV dossier and ECHA decision did not provide sufficient justification and evidence to demonstrate that ADCA is an equivalent concern substance.

Severity of health effects, irreversibility, delay of health effects

CMR substances trigger severe irreversible health effects whereas in the case of ADCA health effects – if any – are not comparably irreversible and not comparably severe.

ECHA states that ADCA as a respiratory sensitiser causes mainly allergy or asthma symptoms or breathing difficulties. But nothing is said with regard to the irreversibility and severeness of these health effects similar to the health effect of CMR substances.

ECHA does not present any data to verify that the delay of health effects after exposure to ADCA is similar to the delay of health effects after exposure to CMR substances.

ECHA does not present any data to prove scientifically that exposure to ADCA results is similar to exposure to CMR in delayed onset of symptoms and persistent symptoms lasting for years resulting in serious social consequences and impairment of quality of life.

Conclusion: With regard to the equivalent level of concern the background document which is based on the annex XV dossier is rather based on assumptions than on scientific evidence.

A key factor affecting the extent to which humans are exposed to ADCA is the physical form of ADCA. ADCA may cause only sensitising effects on the respiratory system when it is used in dry powder form. In all other physical forms (liquid dispersion, paste, granules) ADCA has no sensitising effects. In only 33.3 % of the production processes, EuPC members do use ADCA in dry powder.

ADCA in dry powder form has only sensitising effects if the particle size is between 2 - 10 micron range. Particles with a size above 10 micron are in a non-respirable range for humans and cannot have any sensitising effect.

According to the annex XV report (section 7.2.1): ADCA is manufactured predominantly with a particle size in the 2 - 10 micron range. The particle size specification is based on the study by Kim C., Cho J., Leem J., Ruy J., Lee H., Hong Y. Occupational asthma due to azodicarbonamide. Yonsei Medical Journal 45, No 2, 325-329, 2004.

EuPC is questioning the particle size range 2 - 10 micron. There are different types of ADCA powder on the market used for different applications. Lots of these types have a particle size above 10 micron. Only one single, nearly ten year old study is not enough to give valid information about the correct particle size range in which ADCA powder is nowadays on the market.

The data in the annex XV dossier, which should prove the health effects are of poor quality and are not representative. Corresponding statements have already been made by EuPC in the first consultation (inclusion Candidate List).

The number of reported cases of respiratory disease caused by ADCA in the annex XV dossier is very limited concerning countries (2), number of cases (42).

Studies that have been used for the assessment of health effects are more than twenty years old

Furthermore, the majority of the reported cases are from the period between 1989 and 1993. Since this date, the protection of workers was implemented systematically as defined in the SDSs (respiratory protection mask, gloves, goggles) and in many cases local exhaust ventilation systems, closed systems were installed.

No health risk associated with the handling of ADCA taking current risk management measures into account

The Health Monitoring Data gathered from EuPC show that no company has in the last twenty years ever been confronted with a single health effect clearly related to ADCA.

Workers handling ADCA are regularly checked by medical personnel by examining their lung functions, conducting spirometry and blood tests.

Data of long-term medical monitoring carried out by half of the members of the EuPC Expert Group are available and can be obtained upon special request at the company doctors.

ECHA SHOULD POSTPONE THE DECISION ABOUT FINAL RECOMMENDATION FOR PRIORITISATION

With the same decision ECHA decided to include ADCA in the Candidate List (ED/169/2012), ECHA decided to include two other substances, classified as respiratory sensitisers, hexahydrophthalic anhydride (HHPA) and methylhexahydrophthalic anhydride (MHHPA) on the Candidate List. These two substances were included because ECHA regarded them like ADCA as Art. 57 f REACH substance. The argumentation for the categorisation was based on the same poor arguments and data like that on ADCA.

The inclusion of the HHPA and MHHP was brought to the ECJ on February 2013 (T 134/13 and T135/13) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:129:0026:0026:EN:PDF

The applicants claim that the court should partially annul ECHA Decision 169/2012, because both substances do not meet the Art. 57 f REACH criteria.

First plea in law: alleging manifest error of assessment: respiratory sensitisers are not covered by Art. 57 f REACH. Arguments:

ECHA did not provide sufficient justification and evidence in order to demonstrate that the substances were of equivalent level of concern to a CMR (Cat 1, 2) substance, since:

- CMR substances trigger irreversible effects whereas in the case of the two substances the effects of the respiratory sensitisation are not reversible
- There is no consumer or worker exposure
- The assessment of the substances is old and outdated

Second plea in law: alleging breach of the rights of defence, as the applicants did not have the opportunity to fully defend their case because of the lack of objective criteria for considering whether a substance is of equivalent concern according to Art. 57 f REACH.

Both cases are still pending.

Conclusion: ECHA should not adopt a final recommendation for the prioritisation of ADCA until the cases are resolved. ECHA should not put itself in a position where it makes a recommendation, which is potentially in direct conflict with a pending EJC judgement.

COMMENTS (3) ON THE PRIORITISATION OF THE SUBSTANCE

ECHA justifies the prioritisation of ADCA with a high score number (in total 19 score points) compared to the other substances on the Candidate List.

ECHA assigned 1 score point for intrinsic properties, assigned 9 score points for high volume and further 9 score points for wide-dispersiveness of use. All score points distributed for the three criteria are too high.

1 Score Point for inherent Properties too high *(score range 0 - 4)*

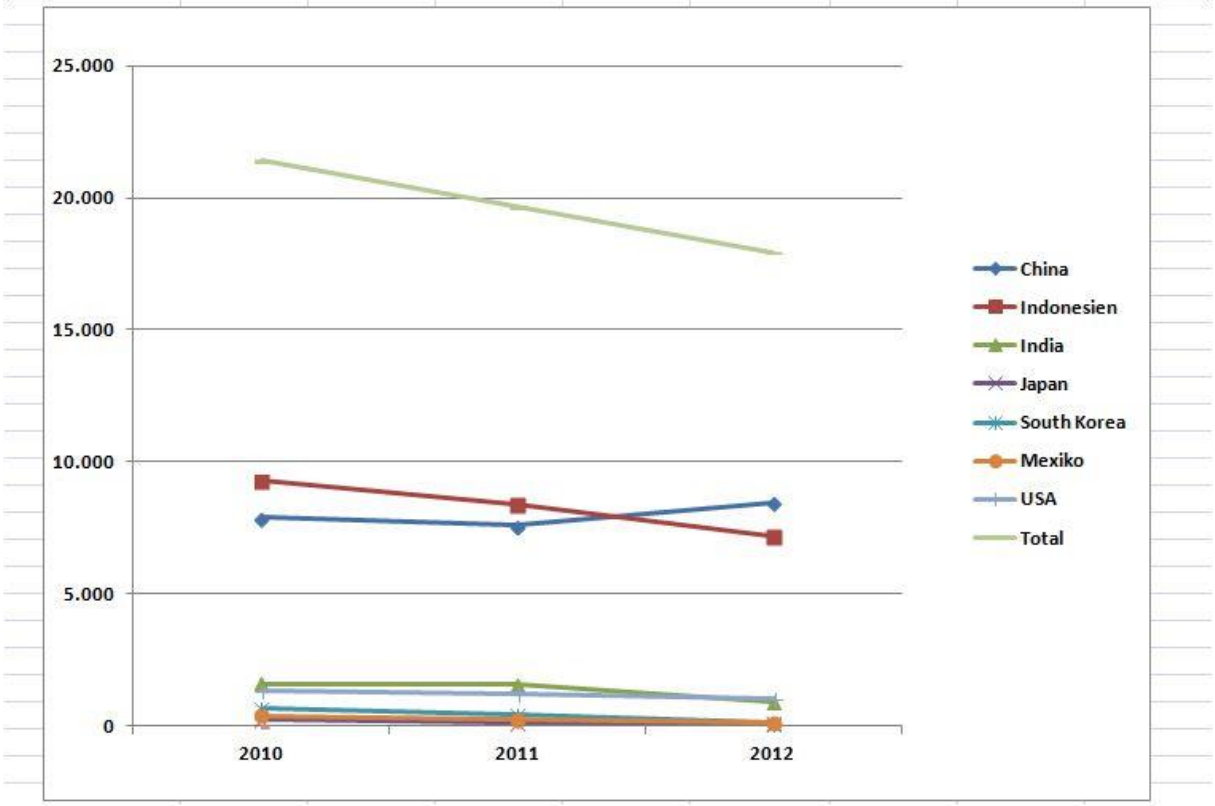
1 score point given for inherent properties is too high. The correct score number should be 0. 1 score was given because no effect threshold exists. At the moment there is some evidence for a threshold but until the consultation deadline too many uncertainties remain.

9 Score Points for Volume too high *(score range 0 - 9)*

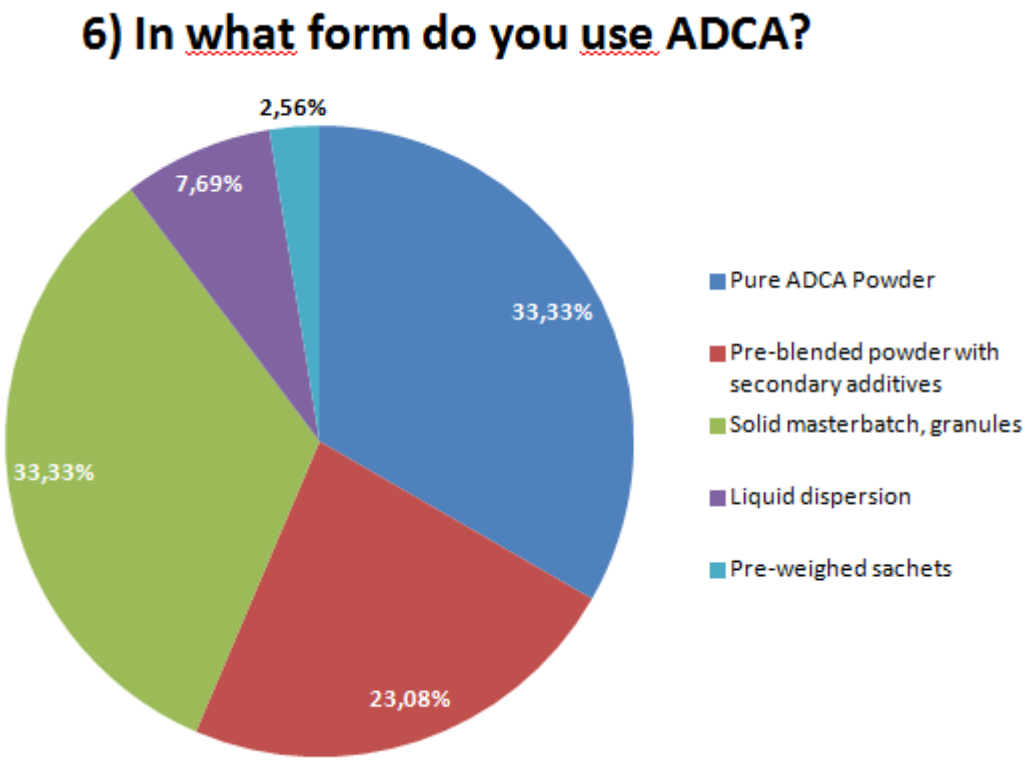
Score 9 is given for a very high volume, i.e. above 10,000 t/a, of imported ADCA. According to EUROSTAT the imported volume in 2012 was 17,941 tonnes

Imports ADCA (Azodicarbonamide) into the EU

	China	Indonesien	India	Japan	South Korea	Mexiko	USA	Total
2010	7.905	9.278	1.602	241	666	400	1.323	21.415
2011	7.592	8.403	1.587	142	438	269	1.214	19.645
2012	8.448	7.180	924	113	107	148	1.021	17.941



ADCA is imported in different physical forms. Only ADCA in dry powder form can be released. Therefore, only ADCA in powder form should be taken into account for the volume. As already mentioned only 33.3 % of the ADCA volume converted by EuPC is in dry powder form. Other forms are mainly solid masterbatches, granules and liquid dispersions.



This reduces the volume below 10,000 t/yr and lowers the score to 7.

9 Score Points for wide-dispersive Use too high *(score range 0 - 9)*

The scoring of the 'wide-dispersive use' criterion has been broken up in the two sub-criteria: 'site-numbers' and 'releases'.

Wide-dispersive Use sub-criteria ‘Site’

3 score points have been given for a high number of sites (score range 0 - 3), i.e. hundreds or more sites, where ADCA is used as a blowing agent and from which ADCA is being released.

The Consultation Background Document refers with regard to the number of sites to the annex VX dossier. The annex XV dossier is in this respect only based on assumptions.

Specifically, the background document states: “Formulations containing ADCA appear to be prepared in industrial settings and then further distributed to downstream users. This suggests a supply chain structure with tens of formulator sites and hundreds of use sites in the EU. Therefore, it appears reasonable to assume that ADCA is used at a high number of sites.”

The way ECHA phrases in uncertain terms (appear, suggests) shows that ECHA has no data, not even conclusive information available about the number of sites in the EU where ADCA is used as a blowing agent.

‘More than hundred uses sites’ is nothing more than an assumption. EuPC is questioning this assumption.

Score points should not be awarded on the basis of assumptions; they have to be awarded on the basis of facts.

Furthermore, the assumptions take into account all sites where ADCA is used. However, only the sites should taken into account where ADCA is used in dry powder; only there release may occur. Therefore, EuPC is considering 2 score points for sites as reasonable.

Wide-dispersive Use sub-criteria ‘Release’

3 score points have been given for release for worker exposure and consumer exposure (score range 0 - 3).

3 score points are generally given for diffuse/uncontrolled/significant potential for release to the environment for worker exposure and for consumer exposure in all steps of the life cycle

3 score points for potential release of ADCA are too high. For workers exposure is insignificant, if it takes place when it is controlled. For consumers exposure can be excluded.

Physical form Key Factor with regard to Exposure

The physical form in which ADCA is used is a key factor with regard to the relevance of the exposure. The use of the substance in other forms than dry powder like paste, liquid dispersion, granules results in only negligible exposure . As already elaborated, only 33.3 % of the ADCA volume converted by EuPC is in dry powder form.

Insignificant and controlled Worker Exposure

Exposures for employees in production areas can almost exclusively happen during production processes. This, however, is mostly only the case in processes with high temperatures within a production plant. Temperatures of about 200 °C are usually required during plastics processing in order to plasticise and form solid plastic granules and plastic mixtures which at the end of a process are made into hard films, profiles and other plastic forms which result in hard plastics as well as plasticised plastics and foamed plastics. On the short way of a few seconds for the plasticised plastic to become a solidly formed product, the plastic has its required high temperature of about 200 °C. In this phase, the blowing and foaming agent ADCA fulfils its intended function and in this process a limited emission of the additive can take place.

In a closed production system, the released ADCA cannot escape and is discharged together with the cooled process air in a controlled manner. EuPC is using closed production systems in 85.5 %.

Open and partially open production processes usually release possible concentrations into the exhaust air which is operated and discharged in many production plants in a controlled manner.

Should the concentration in the production area be too high (compared to the legally specified occupational exposure limit in the UK), the plant operator take process-

related measures in order to keep it under control and below a limit which does not present a risk to the health of the employees in the production area.

There is another possible way of exposure when a factory uses ADCA in powder form and mixes it into the formulation. In 85 % this takes place in a closed system, so there can be no exposure.

If the use of ADCA in powder form does not take place in a closed system, the following Risk Management Measures (RMM) according to the Safety Data Sheets (SDS) provided by the ADCA manufacturers are strictly implemented by EuPC:

General protective measures
Local exhaust ventilation, efficient ventilation in the working area

Respiratory protection
Dust mask, good ventilation, in case of brief exposure or low pollution respiratory filter device (filter P2) are used, in case of intensive or longer exposure self-contained respiratory protective device are used

Protection of hands
Protective gloves

Eye protection
Safety glasses

Body protection
Protective work clothing

ADCA is handled with the above-mentioned RMM only by trained workers. In consequence the workplace exposure is adequately controlled.

Occupational Exposure Limit

The UK introduced an occupational exposure limit of ADCA in 1996 (EH4O/2005 Workplace exposure limits Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations 2002 (as amended), page 17). According to this, a national maximum exposure limit for ADCA is with an eight hour limit value of 1 mg/m^3 and a short-term exposure limit of 3 mg/m^3.

Levels of measured exposure to ADCA in workplaces

With regard to the consultation EuPC tried to collect information about the levels of ADCA workplace exposure in the companies. In other countries there is no statutory regulation; therefore only a relatively small number of companies were able to provide data on workplace concentration. The EuPC member association, Sfec, from France carried out workplace measurements with regard to the UK exposure limit in several industrial sites of its members. The measurements are nearly finalised and up to now all results of all companies are significantly below the UK threshold (<0.1 mg/m^3).

One more similar result from an the UK shows that worker exposure is negligible. The extract of a laboratory report shows a measured value of 0.09 mg/m^3, which only amounts to 9 % of the UK threshold value.

APPENDIX : LABORATORY ANALYSIS

Area	M6 Monomill	Date	30th April 2013

No	Subject	Time ON	Time OFF	Period minutes	Start flow	End flow	Volume litres	Filter Ref	Shift length	Analyte	µg on filter	Result mg/m^3	8hr TWA mg/m^3
05b	Phil Knowles	10:37	12:21	104	2.0	2.0	208	7528	8.00	Azodicarbonamide	19.3	0.09	0.09

Breaks

The sample ran continuously.

Sample description

The sample filter was further analysed for Azodicarbonamide. The operating conditions are the same as those described for sample 05a.

Comments

The result shows that personal exposure to Azodicarbonamide would be at a level of 9% of the workplace exposure limit if no resiratory protection was worn. As respiratory protection was worn the actual personal exposure will be at a lower level than that of the result quoted, with the level of reduction being dependant upon the efficiency of the protection used.

Besides measurement there is a computer-based method for the computation of the exposure under exactly described production conditions. One of the few European experts for such computer-based computations is FABES in Munich, Germany,

whose computer-based model for the migration of substances into food has been legally specified with regulation 10/2011.

Two examples for the exposure of ADCA from PVC rigid films and soft PVC sheets have been successfully conducted in a first model calculation. They are given as confidential attachment as this is proprietary information from FABES who developed this method. The result is comparable with the measured results in the UK.

Conclusion: The data gathered by EuPC show ADCA is predominantly used in closed systems. Where this is not the case and release may occur, the release is negligible and strictly controlled because proper Risk Management Measures (RMM) are implemented. There is no workplace exposure above the relevant UK limit. Therefore EuPC handled ADCA safely for decades.

No Consumer Exposure

The potential exposure of consumers and professionals to ADCA was mainly concluded in the annex XV dossier on the basis of the registered uses as air fresheners and construction chemicals. To the knowledge of EuPC, ADCA is neither used in air fresheners nor in construction chemicals. As it was stated already in the first Consultation (inclusion in the Candidate List) the registration for these uses seems to be mistaken. EuPC understands that the Background Document states that previous registrations, which covered the professional use as a construction chemical and the consumer use as an air freshener, have been withdrawn. The Background Document states also (2.2.2.2.) that the revised registration dossiers now advise against these uses of ADCA.

Only industrial uses of ADCA are actually registered under REACH.

Consumer Exposure to finished products

ECHA did not provide sufficient data to proof consumer exposure from finished plastic articles. Consumer exposure from finished plastic articles is unrealistic. As already explained, ADCA decomposes exothermically to a degree of >99.9 % during processing. Non-degraded ADCA would result in coloration of the final article.

ISEGA GmbH measurements

600 measurements of several parts of plastic articles on their ADCA content recently carried out by ISEGA GmbH, Aschaffenburg, Germany, show a concentration from below detection limit up to 0.1 % w/w in most of the cases.

These findings are in line with the annex XV dossier, section 7.3.4. Consumer Exposure:

“In 2012 the Environment Agency Austria analysed 10 (parts of) plastic articles on their content of ADCA and semicarbazide (SEM). In one article (door seal) an ADCA content of 0.083% (w/w) was detected (limit of quantification (LOQ) = 0.001%). SEM was detected in 8/10 articles ranging from 0.0001% (w/w) to 0.0085% (w/w).”

The annex XV dossier states furthermore in section 9.2.: “No information is available on releases from consumer products during normal handling.’”

In the opinion of EuPC in the case of remaining unreacted small traces of ADCA in finished articles the substance does not release during the life cycle of an article, neither in form of abraded particles nor in the form of dust. ADCA is bound in the polymer matrix in a way that prevents releases.

In the opinion of the EuPC 1 score point instead of 3 score points for ‘releases’ seems to be appropriate.

Conclusion: The use of ADCA has to be considered as a ‘wide-spread’ use but not as a ‘wide-dispersive’ use.

III (4) COMMENTS ON INITIAL REVIEW OF SOCIO-ECONOMIC IMPORTANCE OF ADCA

Possible alternative substances or technologies

Potential alternatives, such as OBSH (vinyl wallpaper, rigid PVC), TSH (sealants), TSSC, 5PT, DNPT, SBC – sodium bicarbonate / modified sodium bicarbonates – (vinyl wall covering, low expansion block foams), isopentane, isobutane and physical blowing agents have been tested in former times or at least considered for substitution by EuPC.

But due to the unique properties of ADCA none of the alternatives works or if it works, the result is a product in far inferior quality.

Currently there are no technically suitable alternatives available, plastic converters need at least 5- 8 years to develop them.

Technical implications:

In the case of insulation materials (cold/hot water and heating pipes), alternative blowing agents would lead to a higher material density. This would result in a significantly higher thermal conductivity. The insulating material would be less efficient, which could only be compensated by using significantly more material (thicker insulation), resulting in additional environmental impact (transportation, disposal, etc.). Also processing / production would consume more space (bigger factories, higher prices for the consumer).

When alternative blowing agents (OBSH, carbonates, etc.) are used, members cannot produce material with regular cell structure which leads to degradation of the mechanical properties and lack of sealing properties. This results from the inappropriate decomposition temperature of these blowing agents.

ADCA brings much larger viscosity reduction than SBC. Further, ADCA shows more rapid bubble expansion rate on leaving the die exit and produces more uniform cells.

For Xldpe foam it is in general possible to use isobutene with Ldpe, but because of loss of the crosslinking characteristic the final product has no equivalent properties, no possibility of thermoforming, loss of tear strength, compression set, temperature resistance.

ADCA Advantages

EuPC notes that ADCA has significant technical, economical and environmental advantages.

ADCA is an efficient blowing agent. The high expansion rate leads to efficiency in the production through low material spending. ADCA substantially reduces the weight of

the finished goods (e.g. automotive sector), which has a very positive impact such as reduction of fuel consumption and consequently reduction of CO2 emissions. In so far, weight reduction contributes substantially to the EU targets regarding the efficient use of energy.

Raw material and energy saving

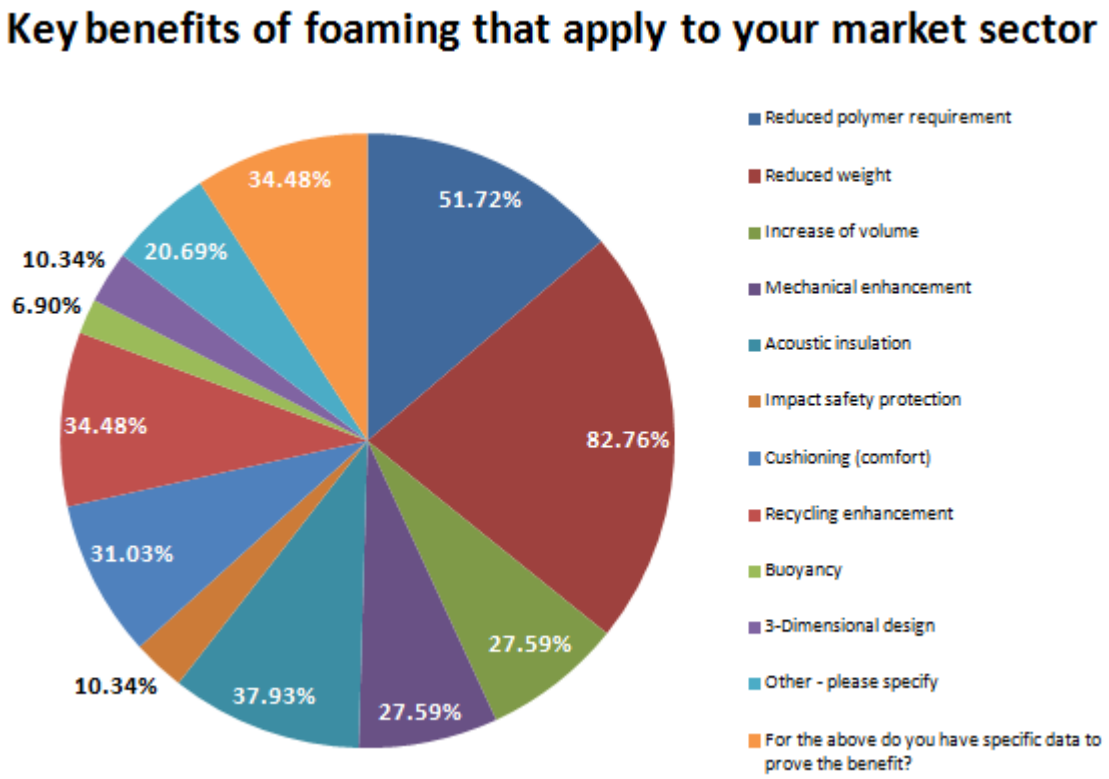
Foaming with ADCA can contribute to raw material savings of over 65 % (e.g. in rigid PVC foam sheets, sewage pipes) or even over 90 % (e.g. in thermal insulation, automotive trim). The use of ADCA as blowing agent to expand insulation material in construction contributes tremendously to the energy efficiently of the buildings. In addition to this, considerable energy savings are achieved through optimal insulation of air conditioning and refrigeration systems.

Positive properties for the final products

ADCA contributes to the consistency and functionality of the final article. The use of ADCA enables fine and consistent cellular structures in the polymers.

A consistent cell structure is particularly important in articles like cable insulation, rigid PVC articles and foam sheets.

The use of ADCA in vinyl wallpaper supports a surface structure which contributes to scratch resistance and washability.



Risk of alternatives health and environment

Most of the alternatives are worse from a (eco) toxicological viewpoint. EuPC has already given detailed information on health, safety and environmental implications on alternatives during the first consultation (inclusion in the Candidate List). The annex XV dossier provides in so far also a lot of useful information.

To avoid repetitions, EuPC only states in this respect that the already known negative impacts of the alternatives to human health and environment are possibly not all. EuPC fears that because of the fact that the alternatives have not at all been as well researched as ADCA, the (eco)toxicological impacts of the potential future alternatives are much larger than assumed so far.

Therefore the substitution of ADCA would constitute into the opinion of EuPC to further health and environmental steps backwards.

Cost implications of using alternatives

EuPC members calculate high research and development costs for reformulation, plant trials, external testing or the adoption of alternative substances.

Where alternatives – with inferior product performance – are available, new equipment has to be installed and additional safety measures for flammable alternative such as OBSH and DNPT have to be installed.

Socio-economic consequences of the inclusion of ADCA in annex XIV

Being a major blowing agent used across the plastics converting industry, the inclusion of ADCA in annex XIV would create a huge economic damage.

ADCA-related products account for almost half of all EuPC members around half of their total turnover.

Some EuPC companies will consider relocating their ADCA-related business outside of the EU in order to avoid the expensive and time limited authorisation.

Several EuPC companies, which are not considering relocating their business outside of the EU, expect to close their ADCA-related business or at least to be adversely affected by authorisation with associated loss of products that cannot be replaced by alternatives. Consequences are: loss of turnover and unemployment.

The smaller EuPC companies, which cannot afford authorisation and cannot survive without their ADCA-related business consider business closure as realistic.

The inclusion of ADCA in annex XIV will result in losses of 274,000 workplaces

One of the most common visions of EuPC companies in the case of inclusion of ADCA in annex XIV is that imports with plastic articles containing ADCA will increase sharply, because the use of ADCA without authorisation in non-EU countries is still allowed for the processing of plastic articles. The non-EU plastic articles containing ADCA brought into the EU market will be much cheaper than the same plastic articles produced in the EU with high costs for authorisation. This will result in a disadvantage for Plastics Converters in the EU. This disadvantage could only be solved in the way that the use of ADCA in the imported plastic articles will be restricted (annex XVII).

Regulatory effectiveness

Authorisation of ADCA has no additional health effects

EuPC is regarding authorisation of ADCA as such as an infringement of the principle of proportionality.

It cannot be seen where authorisation of ADCA in non-respirable forms (paste, liquid) would have any added health benefit since there is – as explained above – no health risk.

Therefore, authorisation is disproportionate in relation to the aims pursued with it.

Restriction of ADCA in annex XVII better solution

EuPC recommends the inclusion of ADCA in annex XVII. Annex XVII should restrict the use of ADCA in dry powder form in the production process for plastic articles. The restriction of the use of ADCA in respirable dry powder form would be sufficient to avoid any health risks.

This restriction will turn the production of foamed plastic articles produced with ADCA to safe processes for all employees in all facilities.

Transitional arrangements (Application date and Sunset date)

In the prioritising suggestion from ECHA, the last date planned for submitting an application (application date) is November 2016 (21 months after inclusion in the authorisation list) – assuming ADCA will appear on Annex XIV in February 2015. The expiry date (sunset date) should be 18 months later according to ECHA's suggestion.

The period between the inclusion of the substance in the authorisation list and the submission of the complete authorisation application is too short. Every company which has to submit an application has never wrote an application request before and has no experience in writing a socio-economic analysis. For the socio-economic analysis many data have to be collected, this cannot be done especially for the SME within the given time frame.

The sunset date is also too short. Many EuPC member companies explained that they already conducted trials in the past to substitute the substance with very unsatisfying results. Our survey clearly indicates technical feasibility problems for all EuPC members. Plastic converters need at least 5 - 8 years to develop feasible alternatives. In contrast to the hint given from ECHA, EuPC is of the opinion that the decision about the adequate date for the sunset date should particularly take into account the existence of suitable alternatives. Otherwise EuPC members cannot continue the production with all negative consequences like product line loss, sales losses, less turnover and job losses. The lack of alternatives is of course a viable reason for prolonging the proposed sunset date and even more so if it is of importance for the authorisation application in a later stage.

Uses (or categories of uses) exempted from the authorisation requirement

EuPC agrees with ECHA; there is 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 REACH.

Review periods for specific uses

No comments from EuPC