CLOSED LOOP SYSTEM **AS A TECHNICAL ALTERNATIVE PROCESS OR PROCEDURE FOR SAFELY HANDLING** ***6-[(C10-C13)-ALKYL-(BRANCHED, UNSATURATED)-2,5-DIOXOPYRROLIDIN-1-YL]HEXANOIC ACID***

PUBLIC VERSION

LEGAL NAME OF SUBMITTER(S): **IPI GLOBAL LTD**

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1. ALTERNATIVE ID AND PROPERTIES

It is very well recognized that closed loop system technology reduces the exposure of the operator below the threshold recommended by the EU as confirmed by our customers and the HSE study and that it is in agreement with the latest amended EU directives for CMD 2004[1] and in general with the (89/391/EEC) of 12 June 1989[2] and the 89/24/EC of 7 April 1998[3].

2. TECHNICAL FEASIBILITY

Product profile.
The valve-coupler system allows the transfer of liquids from one container to another (for example, from a reactor to an IBC of 1000 litres, to drums of different capacity and down to 25 litres and vice versa) in a closed system loop with a vapor recovery option, protecting the operator and the environment.
The valve has a dual function.
The first is a cap (it falls into Group I, according to International Carriage of dangerous goods Regulations, ADR).
The second is to open the liquid transfer circuit when the coupler is inserted.
Our closed loop system technology ***has been shown to reduce exposure below the threshold recommended*** for Carcinogenic, Mutagenic, Reprotoxic and dangerous chemical liquids as reported in the Scientific support section.
Technical information.

Couplers

Valves

2” BSP 56x4

The valve can be integrated into metal drums or IBCs and plastic drums with the appropriate 2”BSP, 56x4mm or 2.5” American Buttress internal thread.
Connection size:
Basic Coupler product outlet: 1” BSPP or RG (female)
Basic VR Coupler vapor recovery: ¼” BSPP or RG (female)
Fill Head/HD Coupler product out/inlet: 1” NPT (male)
Fill Head/HD Coupler vapor recovery: ¼” NPT (female)
The attachment of the dry break coupler enables quick and safe transfer of hazardous product and its vapors from drum to dispense equipment.
Connection between valve and coupler could have a different pin arrangement of 3 or 4 pins in order to avoid cross contamination of two different chemicals.
Flow rate from approximately 18 US Gallon/min. to 24 US Gallon/min (68 to 90 litres /min).
Valve and coupler material are at the moment in Stainless steel 304, 316 or in Nylon.
Residual amount of product for all closed systems is 1 ml.
Downtube in stainless steel 304 or 316; HDPE; HDPE static dissipating
Seal material in EPDM, Viton, Aflas, FKM-HiPer or Simrez

3. Scientific support from HSE

IPI Global Ltd closed systems technology are in accordance with the latest EU Directives [1],[2],[3],[4],[5],[6] of worker and environment protection from hazardous chemicals such as carcinogens, mutagens and reprotoxins as illustrated in a case study on the handling of Hydrazine Hydrate (Substance of very high concern (SVHC)) from the Government Health and Safety Executive (HSE).

http://www.hse.gov.uk/cancer/cancer-case-study1.pdf

The result was a completely enclosed and automated handling, transfer and storage system which eliminates the risk of exposure to the company’s production staff under normal operating conditions.
In fact, the exposure limit for Hydrazine Hydrate is **0.02 ppm** and they monitor the air using a hydrazine meter, also the Health and Safety Laboratory (HSL) came to site many years ago and started some biological monitoring of the employees for Hydrazine Hydrate.
They also have a full yearly medical where they look for blood abnormalities and test organ function. They haven’t had any employee with any issues when working with Hydrazine Hydrate.
The video showing how our complete closed system has been successfully under scientific scrutiny from the UK Health and Safety Executive (HSE), demonstrating a high level of security and how it is used is narrated by OQEMA Ltd (formerly Lansdowne Chemicals) at the following link:

https://www.youtube.com/watch?v=DMC99Vn2UHM&

4. ECONOMIC FEASIBILITY

In the light that EU studies have shown that *"at least 32 million workers are exposed to carcinogens and work-related cancer kills 10 people per hour"* and the connected direct costs *"Direct costs of work-related cancer in terms of healthcare and productivity losses amount at least to some 4-7 billion EUR per year"* and indirect costs *"The indirect costs may reach as much as about 334 billion EUR (242 – 440) each year"*and "*different studies prove that the employer will have a return in double for every euro spent on occupational safety and health"* [7].
From the HSE scientific study, it is clear how it could be beneficial to use a closed loop system technology also for handling ***6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid*** to reduce exposure significantly below OELs.

I would like to bring to your attention that the closed loop technology can also help compliance with the EU Circular economy[8] stipulations and amended EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 94/62/EC of 20 December 1994 on packaging and packaging waste[9] with the latest Commission Implementing Decision (EU) 2019/665 of 17 April 2019[10] and the UN SDG[11] to protect the environment reducing the amount of plastic, metals, water, raw material, energy, etc. and gives a significant economic return for companies.

In fact, one of the impediments for reusing a plastic container, for example an IBC is contamination (the same concept is valid for drums and other containers).

Installing valve in the containers eliminates the risk of contamination because the liquid (and the vapors associated) can only be transferred from the container with coupler (only for emptying at the client site).

I leave you to judge the economic benefit in using our closed loop system while I will bring to your attention the more significant and priceless advantages for ourselves and our planet:

Reusing plastic (or metals).
Saving water for washing the containers (for example IBCs 1000 litres, drums 200 litres, etc.)
Saving energy.
Saving raw material.
Reducing CO_2

Other significant advantages are:
Supplier of chemicals and clients saves space for the containers.
This circle loop allows companies to retain their clients at least for 5 years.

Last but not the least is reducing the exposure to dangerous chemicals (such as CMR chemicals and/or other dangerous chemical liquids) to the operator.

5. HAZARDS AND RISKS OF THE ALTERNATIVE

Compatibility with hazardous chemicals is a must.
Tests must be conducted to ensure suitability.
Operational training must be given.

6. AVAILABILITY

The System is already available from the manufacturer

7. CONCLUSION ON SUITABILITY AND AVAILABILITY OF THE ALTERNATIVE

We are proposing a Technical alternative to the handling recommendations provided in this document for reducing exposure to ***6-[(C10-C13)-alkyl-(branched, unsaturated)-2,5-dioxopyrrolidin-1-yl]hexanoic acid*** significantly below OELs in accordance with the EU[4],[5],[6] directives on carcinogens and mutagens – the IPI closed system has been proved effective for handling CMR liquids in Europe.
These Directives clearly acknowledge the usefulness of a closed system for the protection of workers. In fact, it is specifically mentioned that *"where possible, a carcinogenic (mutagenic and reprotoxic) substance should be substituted with a less-hazardous alternative – otherwise carcinogens (mutagenic and reprotoxic) must, so far as is technically possible, be manufactured and used in a closed system to prevent exposure of workers".*
Together with the OQEMA-HSE study on Hydrazine Hydrate (Carc.1B) with level below 0.02 ppm, Archroma exposure result for Formaldehyde (carc.1B) with level around 0.03 ppm and SAFECHEM exposure to Tetrachloroethylene 25 times below the established level recommended, it confirms that using our closed loop system can help to reduce drastically the exposure of the operator and the environment even further below the threshold recommended by scientists and EU and World Regulatory Agencies.
Moreover, closed loop technology can also help compliance with the EU Circular economy[8] stipulations and amended EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 94/62/EC of 20 December 1994 on packaging and packaging waste[9] with the latest Commission Implementing Decision (EU) 2019/665 of 17 April 2019[10] and the UN SDG[11] to protect the environment reducing the amount of plastic, metals, water, raw material, energy, etc. and gives a significant economic return for companies.

8. OTHER COMMENTS

IPI Global Ltd are REACHReady Approved Suppliers and are specialists in supplying closed loop equipment (valves system and/or containers) for the safe storage and transfer of toxic and hazardous chemical liquids - www.ipi-global.com and are in accordance with the latest EU Directives [4],[5],[6] of worker and environment protection from hazardous chemicals such as carcinogenic, mutagenic and reprotoxic liquids.
IPI Global Ltd have 20 years of experience in supplying completed closed systems

9. REFERENCES

Our closed system technology is already used for handling other chemicals such as Formaldehyde, Isocyanates, Biocides, Solvents, Caustic Soda, Ammonia, Halogenated compounds, flammable, etc. and other carcinogenic, mutagenic or reprotoxic.
The video showing how our closed loop system technology can be used for safely transferring hazardous and/or toxic chemical liquids such as Hydrazine Hydrate (OQEMA), Methyl Iodide, Dimethyl Sulphate (Vinyl), Tetrachloroethylene (SAFECHEM, CSC JÄKLECHEMIE) has been showed during our presentation at Chemspec Europe 2018, 2019 and ChemUK 2019 as per invitation from REACHReady/CIA.

Video OQEMA:
https://www.youtube.com/watch?v=DMC99Vn2UHM&

Video Vinyl:
https://www.youtube.com/watch?v=yfH_W_Ep1mQ

Video SAFECHEM / CSC JÄKLECHEMIE:
Tetrachloroethylene: https://www.youtube.com/watch?v=T_JHJfGUknc

Thanks to our closed system loop technology, Companies have reduced the operator and the environment exposure of CMR and other hazardous chemical liquids below the established level recommended and also, as well as OQEMA, SAFECHEM, Vinyl and others, have reduced the amount of containers per year with clear economic and environmental advantages for the company and the wider world.

The HSE study result has been published on "The business case for engineering in health and safety – IOSH 2013" [12] and "IET Health and Safety Risk Management 2017" [13] as an *…Innovative engineering control to eliminate their workers' and customers' potential exposure to Hydrazine Hydrate, a carcinogen…*

Recently the HSE Study has been published by TNO (Dutch Scientific Research Organisation) on the road map on carcinogens[14] as part of the programme of the EU-OSH 2018–19 Campaign: Healthy Workplaces Manage Dangerous Substances

10. APPENDICES

[1] DIRECTIVE 2004/37/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCILof 29 April 2004on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council

[2] COUNCIL DIRECTIVE of 12 June 1989 on the introduction ofmeasures to encourage improvementsin the safety and health of workers at work (89 / 391 /EEC)

[3] COUNCIL DIRECTIVE 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

[4]DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Text with EEA relevance) {SWD(2016) 152 final} {SWD(2016) 153 final}

[5]DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Text with EEA relevance) {SWD(2017) 7 final} {SWD(2017) 8 final}

[6] DIRECTIVE (EU) 2019/130 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 January 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

[7] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Safer and Healthier Work for All - Modernisation of the EU Occupational Safety and Health Legislation an

[8] COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS on the implementation of the circular economy package: options to address the interface between chemical

[9] EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 94/62/EC of 20 December 1994 on packaging and packaging waste

[10] COMMISSION IMPLEMENTING DECISION (EU) 2019/665 of 17 April 2019 amending Decision 2005/270/EC establishing the formats relating to the database system pursuant to European Parliament and Council Directive 94/62/EC on packaging and packaging waste

[11] 17 Goals to Transform Our World

[12] The business case for engineering in health and safety - IOSH

[13] IET Health and Safety Risk Management 2017

[14] road map on carcinogens