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From Vice President Desk

Dear Friends,

The monsoon season is special globally as it brings in the rain for harvesting as well as providing drinking water for all of us. We wish everyone a Happy Monsoon.

This issue of IPI Journal has a wide spread of articles covering chemical reactions, medical plastics, sustainability, and contemporary topics. We have an interesting interview with Erik Solheim from World Resources Institute where he shares his perspective on plastics.

As most of you are aware, single-use plastics for specific applications have been banned in India, IPI had participated in multiple stakeholder meetings and seminars to address the situation from the industry, and feel free to contact the IPI office in case you have any queries on the same.

We wish you a happy reading.

Kind Regards,

Sriman Banerjee
Vice President,
President Board, IPI

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Inside

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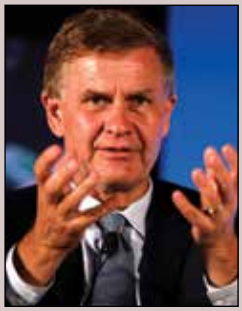
Leader's Speak

Interview for IPI Journal

Erik Solheim,
Senior Adviser -
World Resources Institute &
President - Belt and Road Green
Development Institute, Beijing



1. **Can you share about yourself and World Resources Institute.**

   World Resources Institute is the lead global think tank for the environment. Its headquartered in Washington but has branch offices all over the globe, including in Delhi. I am mainly working with World Resources Institute to promote green development

2. **Plastics are seen as a boon & bane and have been one of the pillars of economic growth, raising food security, healthcare opportunities, etc.; what are your thoughts.**

   Plastic was a miracle material when it first appeared in the 1950s. It could help us conserve food longer, protect against diseases, make cars and aircraft lighter and served a fancy of other good purposes. But as often happens to us humans - we got addicted and started using too much and worse - dispatched into nature.

   We now have a triple plastic crisis- environment, economy, and health. Plastics have an impact on animals and nature. It also has a potential economic threat in tourist hotspots and elsewhere.

3. **Circular economy is key to climate change. Can you share some successful examples concerning plastics?**

   We need a triple answer to the plastic crisis. Refuse products we don't need like straws, cups, or cutlery. Such products are now abandoned in India as well as the EU. Additionally, we need to be more innovative and make plastics from natural materials like potatoes or sugarcane. But most importantly we must start industrial-scale recycling of plastics in a circular economy. Many companies in developing countries recycle plastics into plastic products like chairs and tables. Ghana is one example. In developed countries, plastics is normally not deposited at landfall but recycled as fuel in Denmark and Spain for example, or burned to create energy in many other places.

4. **What are the challenges to meeting net-zero objectives by 2040.**

   We have all the technologies, finances, and policies we need to reach net-zero. The main issue is to change our thinking and to make sure change happens at speed. We should see the environmental crisis as a big opportunity to create jobs and drive business. Moving from coal to solar, or from fossil fuel cars to electric cars, are not costs but wins for both economy and ecology. Tree planting and ecological agriculture are also triple wins - good for both business, Mother Earth, and people well-being

5. **How can the plastic industry contribute to a better environment.**

   The plastic industry must fully support the triple policy of avoiding unnecessary plastic products, being more innovative in design and recycle the remains at an industrial scale. The good news is this is all feasible. The plastic industry needs to take the lead in the green shift.

Practical Approach to Prediction and Prevention of Runaway Reactions

Authors:
Dr. Kalpana Deshmukh and Mr. Vinayak Londhe

Abstract

Exothermic processes carried out in chemical industries can lead to runaway reactions leading to casualties and property loss. Conventional Prediction and Prevention techniques of runaway reactions are costly and not suitable for MSME units and, therefore, avoided. For this reason, we often witness accidents in MSME units due to runaway reactions. No cost theoretical prediction method and simple practical prevention techniques are suggested to mitigate such accidents.

1. Introduction:

Over the years, society has been greatly benefited from the chemical process industries. However, the chemical processes also pose accidental risks such as fires, explosions and toxic material releases. One of the major accident risks in chemical processes such as polymerization, nitration, sulfonation, epoxidation etc. is due to exothermic nature of these reactions that generates high heat of reactions in the processes. Such runaway reaction will cause boiling over of toxic materials and its release in atmosphere and also bursting and splintering of fragments of reaction vessels due to increase in pressure.

In MSME chemical process industries, we have been often witnessing such accidents in chemical process industries causing huge loss to properties and injuries or loss of human lives. These units are not well equipped with means to predict and, therefore, provide preventive measures to avoid such hazardous reactions. It is, therefore, of great need to predict and prevent such accidents due to runaway reactions by means within reach of MSME units. This requires simplified techniques of prediction of heat generation and heat removal.

Modern advanced predictive experimental calorimetric techniques for determination of heat generation are very costly and also time consuming, generally suitable for newly developed molecules. Reaction processes carried out in MSME units are usually known and prediction of heat generation can also be made by evaluating thermal kinetics of the reaction theoretically1. Heat removal capacity of cooling system can be calculated with detailed engineering design data calculations or with simple experiment.

In the present paper, application of reaction heats to process safety analysis and simple and reliable methods of computation of heat generation and heat removal by combination of theoretical estimation and simple experiments is presented that can be easily implemented by MSME units.

2. Runaway Reaction

Heat generated by exothermic reaction will increase the reaction mass temperature proportional to generated heat and this increase in temperature may initiate thermal exothermic decomposition of reaction constituent thus increasing the temperature further. When the overall temperature of reaction mass exceeds certain limit, runaway will occur. Various temperature characteristic values in relation to runaway reaction are given below:

2.1. MTT: Maximum Temperature for Technical Reason

This is temperature of boiling point of reaction mass constituent in open system or temperature of maximum permissible pressure in close system. If the reaction mass exceeds this temperature, MTT, runaway will occur either in the form of release of boiling hazardous chemicals in the atmosphere in open system or in the case of close system, leading to rupture of reaction vessel and splintering of fragments of reaction vessel along with release of hazardous chemicals in the atmosphere.

2.2. ΔT_{ad}: Adiabatic Temperature Rise

This is increase in temperature of reaction mass only due to the heat of reaction under adiabatic condition, meaning no heat is given or taken from the reaction mass. This Tad can be calculated by following Equation:

$$\Delta Tad = Qr / Cp, \text{ where (Equation 1)}$$

Q_r is heat of reaction generally expressed in the unit of Kilo Joules (KJ) or Kilo Calories (KC) per mole of reactant and C_p is specific heat capacity of reaction mass generally in the unit of Joules/ gm°C or Calories / gm°C.

High ΔT_{ad} generally means high energies that result in fast runaway or thermal explosion. Assessment of severity of a runaway reaction based on ΔT_{ad} is presented in Table 1.

ΔH (J/g)	ΔT_{ad} (°C)	Severity
Less than −500	>250	High
$-500 < \Delta H < -50$	$25 < \Delta T_{ad} < 250$	Medium
More than −50	<25	Low

Table 1. Classification of the Severity of Decomposition Reactions According to the Corresponding Adiabatic Temperature Rise (Assuming a Cp of 2 J/(g K))

2.3. MTSR: Maximum Temperature of Synthetic Reaction

This is the temperature a synthetic reaction will reach in case of cooling failure and expressed as

$$MTSR = Tp + (Xac*\Delta T_{ad}), \text{ where (Equation 2)}$$

Tp is reaction process temperature, Xac is unconverted fraction of reactant at the time of cooling failure and ΔT_{ad} is adiabatic temperature rise of reaction. In worst scenario, MTSR at maximum level will be when cooling failure is at start time and Xac equal to one

$$MTSR = Tp + \Delta T_{ad} \text{ (Equation 3)}$$

T_b: Boiling Point of the Reaction Mass

T_d: Temperature at which rate of decomposition of reaction mass constituent becomes hazardous.

3. Application of Reaction Heats to Process Safety Analysis

Stoessel has described the risk associated with chemical processes using five scenarios as shown in Fig. 12.

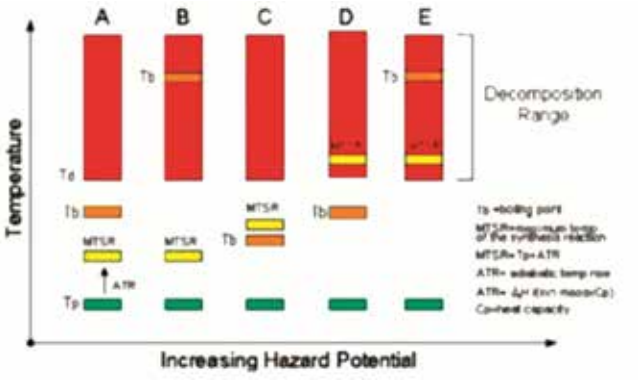


Figure 1 Five scenarios that depict the relative risk associated with chemical processing

Risk is analyzed with regard to the relationship between the desired process temperature, T_p, adiabatic temperature rise ΔT_{ad} for the reaction, boiling point of reaction mass, T_b, temperature of hazardous decomposition, T_d, and maximum temperature of synthetic reaction, MTSR. The potential hazard increases from left to right.

In scenario A, even if all the heat is released instantaneously, the temperature will reach MTSR, which is below boiling point of reaction mass, T_b, and hazardous decomposition temperature, T_d. So, this is thermally safe process. In scenario B also MTSR is below Tb and T_d, though Tb is higher than T_d. This is also thermally safe process unless input of extra heat in the reaction mass leading to decomposition.

In scenario C, MTSR exceeds boiling temperature Tb, and there is possibility of overpressure in reactor due to boiling vapor pressure. However, there is no risk of hazardous decomposition since T_d is above MTSR. Controlling reaction rate by measures such as controlled dosing of a reactant may suffice to bring MTSR below T_b.

In the case of scenario D, MTSR exceeds both Tb and Td. Hazardous decompositions leading to higher temperature and pressure may take place. Some evaporative cooling may take place since T_b is lower than MTSR. However, reaction controls and protection are necessary. In scenario E, MTSR exceeds Td but not Tb. In the event of loss of control significant decomposition will take place leading to hybrid pressure effect of gaseous decomposition and high temperature vapor pressure.

3.1 Prediction and Prevention of Runaway Reaction

As seen above, the risk assessment prediction of runaway can be made if T_p, T_b, T_d and MTSR, are known. T_p is desired reaction temperature and Tb is known from reaction experiment. Td can be found out from data banks for known reaction ingredients or determined by simple Differential Scanning Calorimetry (DSC) experiment of reaction mixture. MTSR is determined from Equation (3) by calculation of ΔT_{ad} from Equation (1). To calculate ΔT_{ad}, heat of reaction Qr and specific heat capacity Cp should be known. Cp values are readily available from data banks or generally assumed 2.0 joules/gm K for organic compounds. Thus, if heat of reaction, Q_r, is assessed, ΔT_{ad}, MTSR and thereby severity of runaway reaction can be predicted from Stoessel diagram.

Once the severity of exothermic reaction is known, one needs to mitigate the severity by removing heat from the process to keep the temperature of reaction within safe limits of preventing boiling over, decomposition and pressurization. To prevent runaway reaction, therefore, cooling capacity of the process needs to be assessed. And, if this cooling capacity is not adequate, measures to boost the cooling capacity need to be provided for the existing system.

3.2 Prediction of Runaway Reaction

As seen above, severity of runaway reaction can be assessed if reaction heat, Qr, is known.

Two methods are used to determine this reaction heat, Qr.

1. Calorimetric experimental determination.
2. Theoretical estimation from thermal data of reaction

Modern advanced predictive calorimetric experimental techniques for estimation of heat generation are very costly

and time consuming, generally suitable for newly developed reactions. Reactions carried out in MSME units are usually known and heat of reaction can be estimated theoretically from thermal kinetics of the reaction. Both techniques have some limitations and can be considered with safety margin. Theoretical estimation techniques are more suitable for MSME units and considered here.

3.3 Theoretical Estimation of Heat of Reaction, Qr, and Assessment of Severity

Theoretical estimation of heat is long known and is part of text books now. It is calculated as Sum of Heats of Formations (ΔH_f) of Products of reaction minus that of reactants. Heats of formations, ΔH_f, of compounds are readily available from data banks.

For better understanding, we will now work out theoretical estimation of Q_r and assessment of reaction runaway severity with case example of heat of epoxidation of Butene Diol with hydrogen peroxide.

Butene Diol+Hydrogen Peroxide $\longrightarrow$Epoxy Butane Diol + Water

C4H8O2 (88) + H2O2 (34) $\longrightarrow$C4H8O3 (104) + H2O (18)

ΔH_f= -342.6 + ΔH_f= -187.8 $\longrightarrow$ ΔH_f= -436.3 + ΔH_f= -285.4 KJ/M

Therefore, Heat of Reaction, Q_r, will be = -436.3 -285.4 + 342.6 +187.8 = -191.3 KJ / M. Negative sign means heat will be generated in the reaction. Thus, 191.3 KJ (45.72 KC) of heat will be produced by epoxidation of one mole, that is 88 gms, of Butene Diol, for reaction mass of 122 gms.

3.4 Runaway Risk Analysis for above example:

Calculation of ΔT_{ad}:

Once heat of reaction is known, ΔT_{ad} can be calculated from Equation (1). Assuming C_p for diol of 2 joules/gm K and that of water is 4.182 joules/gm K, specific heat capacity of reaction mass will be (104*2) + (18*4.182) / (104 +18) = 2.322 J / gm K

Therefore, ΔTad = (191.3 * 1000) / (122 * 2.322) = 675.3 K

That is with no heat provided to or removed from the reaction mass, temperature of reaction mass will increase by 675.30C, assuming reaction temperature of 250C, MTSR will be

MTSR = 675 + 25 = 7000C

From the criticality class Table 1 and Stoessel diagram, it is clearly catastrophic reaction falling under Scenario D of Stossel diagram. All preventive measures such as efficient cooling, controlled dosing etc. need to be provided.

4. Prevention of Runaway Reaction

Once severity of runaway reaction is known, the first step to prevent it is to provide for efficient cooling of reaction mass so that all heat produced in the reaction mass is removed and temperature of reaction is maintained at desired process temperature, Tp. This may be achieved by circulating cooling media along reaction container surface area to remove heat from reaction by heat transfer from reaction mass.

The quantification of this heat transfer is provided in following equation (4).

$Q = U*A*\Delta T_{lm} = m*C_p*(T2 – T1)$ (Equation 4)

where,

Q is heat transferred under steady state from reaction vessel , KJ / sec U is overall heat transfer coefficient, KJ / (sec*m²*°C) A is area available for heat transfer, m²

ΔT_{lm} is log mean temperature difference $= \frac{(T-T1)-(T-T2)}{\ln (T-T1)/(T-T2)}$ °C

T is temperature of reaction mass in the vessel,°C. T1 is inlet temperature of cooling fluid, °C. T2 is outlet temperature of cooling fluid, °C. m is mass flow rate of cooling fluid, Kg / sec and Cp is specific heat capacity of cooling fluid, KJ/Kg°C.

5. Conclusion

The required cooling area for the exothermic reaction can be calculated from Equation 4 and if it is adequate, no runaway will occur. However, if the available cooling area is less, runaway reaction is predicted and other measures such as cooling media at lower temperature or modifications to the process with reaction mass dilution with high Cp solvent, control dosing of reactant etc. may be considered to prevent the runaway reaction.

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1. "Chemical Reaction Hazards" by Barton J and Rogers R., Institution of chemical engineers: Rugby UK, 1996.
2. "What is your Thermal Risk?" by Stoessel F. Chem. Eng. Prog., 1993; Volume 89 (10), 68-75.

Innovative polymer solutions for healthcare

Niraj Dixit
(Senior Application Development Engineer),
Asia South Packaging, Borouge Pte Ltd. and

Nitin Bokarey
(Senior Manager, Market Development)

Plastics are an indispensable part of our everyday life and are used in a multitude of applications that add convenience, comfort, health and safety to societies across the world.

Due to the COVID-19 pandemic, global demand has surged for medical devices and supplies, and the industry continues to evolve with the latest trends and innovations to enhance the production, quality and consistency of medical products. With the advancements, plastics continue to play an essential role in adapting to the evolving needs of the medical sector.

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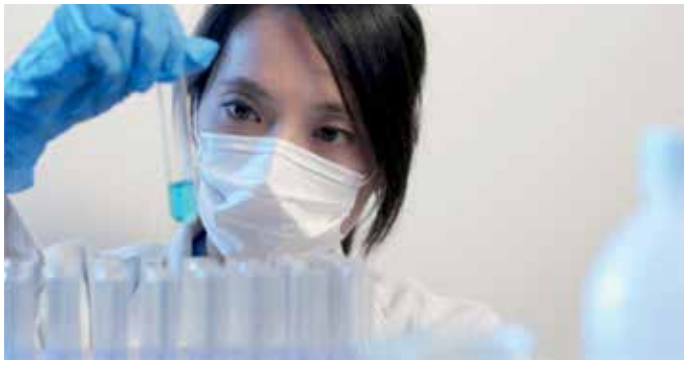

The combination of versatility, cost competitiveness and easy shaping during conversion make polypropylene (PP) and polyethylene (PE) the materials of choice for medical applications. As medical devices evolve, the right materials are required to meet the stringent demands of the application in order to secure the device and its contents and safeguard the health of the patient.

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The Bormed™ Concept ensures that the customer's healthcare business is carried out in a reliable and meaningful way with respect to the needs of the industry. Going beyond pharmacopeia compliance documentation and technical service, the Bormed™ Concept gathers insights from value chain partners and incorporates these into all Bormed processes, from product conception to production, procurement, support and distribution.

The Bormed™ concept is based on the principles of service, commitment, and conformance.

- It encompasses product conception to production, procurement and support, to deliver consistency of the product recipe via rigorous control procedures.
- The Bormed™ directive governs detailed operating instructions for the development, production, storage and delivery to the end customers of Bormed™ products.

- For peace of mind, pharmacopeia compliance is achieved through regular external testing by European Pharmacopoeia (Ph. Eur), US Pharmacopeia Convention (USP) and ISO 10993. All grades are listed in the US Drug Master Files (DMF) and follow VDI 2017 guidelines for medical-grade plastics.

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Plastics continue to play a continuing role in the healthcare sector, bringing benefits such as versatility, improved safety and cost efficiency, to medical applications.

The Bormed™ portfolio is constantly growing and comprises polyolefins for medical devices, pharmaceuticals and diagnostic packaging with superior technical performance. With cutting-edge technological expertise and ongoing innovation, Borouge is committed to producing polypropylene and polyethylene of the highest quality and meeting customers' strictest requirements.

For more information, visit www.borouge.com. Contact – Nitin.Bokarey@borouge.com ; Niraj.Dixit@borouge.com

"Regulatory Testing of Medical Grade Plastics, Rubbers & Packaging Material"

Dr. Manish A. Rachchh

Director (R & D) and CEO of Accuprec Research Labs Pvt. Ltd., Ahmedabad, Gujarat, India.

Abstract:

This paper describes that how changes in regulatory environment or regulatory policies affects the medical device segments. In the present article, we have specify the medical device (Class A, B, C & D), which are notified and/or going to be notified and regulated in India by CDSCO and also specify the required tests for Raw material and Components of Medical Devices. CDSCO has published 24 broad categories comprising 2500+ medical devices, out of which class A & B devices will come into the regulation from 01.10.2022 and class C & D devices will come into the regulation from 01.10.2023. So all medical devices and its raw material manufacturer have to start doing pre-preparation for the compliance of the same by starting appropriate testing as recommended by Indian MDR 2017.

Introduction:

Rapid growth and updation in medical device regulatory environment is a worldwide phenomenon. The primary purpose of implementing regulatory systems for medical devices is to protect public health and ensure safety and performance. Medical device testing is the process of demonstrating that the device will reliably and safely perform during its intended use.

Definitions (As per CDSCO MDR Rules, 2017):

1. **Medical Device:** All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of –
   i. Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
   ii. Diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
   iii. Investigation, replacement or modification or support of the anatomy or of a physiological process;
   iv. Supporting or sustaining life;
   v. Disinfection of medical devices; and
   vi. Control of conception
2. **Raw material:** Raw or unprocessed materials are basic components used in the manufacture of medical devices and their components. There are a wide range of raw materials available to organizations manufacturing medical technology, including additives, alloys, ceramics, and gels.
3. **Packaging material:** Packaging Material is any article or substance which is intended to use to protect the medical device from external environment. It is made up of known and traceable materials. Non-toxic, non-leaching and odorless. It is free of holes, cracks, tears, creases and localized thinning.
4. **Medical Grade Plastic:** It refers to plastics designed to make medical products. It is high wear, temperature resistant and corrosion resistant. It is used in manufacturing many types of medical devices and equipment from MRI machines to diagnostic wands as well as medical and surgical tubing.

Table 1: List of Medical Device are notified and regulated in India by CDSCO

Sr. No.	Name of the Device	Notification Number	Date of Notification
1	Disposable Hypodermic Syringes	GSR 365 (E)	17-03-1989
2	Disposable Hypodermic Needles	GSR 365 (E)	17-03-1989
3	Disposable Perfusion Sets	GSR 365 (E)	17-03-1989
4	In vitro Diagnostic Devices for HIV, HBsAg and HCV	GSR 601 (E)	27-08-2002
5	Cardiac Stents	S.O. 1468 (E)	06-10-2005
6	Drug Eluting Stents	S.O. 1468 (E)	06-10-2005
7	Catheters	S.O. 1468 (E)	06-10-2005
8	Intra ocular lenses	S.O. 1468 (E)	06-10-2005

9	I.V. Cannulae	S.O. 1468 (E)	06-10-2005
10	Bone cements	S.O. 1468 (E)	06-10-2005
11	Heart Valves	S.O. 1468 (E)	06-10-2005
12	Scalp Vein Set	S.O. 1468 (E)	06-10-2005
13	Orthopedic Implants	S.O. 1468 (E)	06-10-2005
14	Internal Prosthetic Replacements	S.O. 1468 (E)	06-10-2005
15	Ablation Devices	S.O. 237 (E)	25-01-2016

CDSCO has published broad 24 category of medical devices as per their healthcare categories, which are as of now non-regulated and listed as non-notified devices. Under this 24 categories approximate 2500+ devices are fall, which come into class A to D.

The registration of all such non-notified class A, B, C & D devices have been kept voluntary by CDSCO for a period of 18 months w.e.f. 1st April 2020 i.e. till 30-09-2021.

Voluntary Registration of class A & B devices shall be followed by mandatory registration after 30-09-2022.

From 01-10-2022, all class A & B devices will fall under CDSCO licensing regime.

Similarly, the registration of all such non-notified class C & D devices shall be followed by mandatory registration for 24 months after 18 months voluntary registration period is over i.e. 01-10-2021 to 30-09-2023.

From 01-10-2023, all such class C & D devices will fall under CDSCO licensing regime.

In brief, any item that is going to be used in the hospital / healthcare sector for diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder will come under the regulation of CDSCO from 30.09.2022 (Class A & B) OR 1.10.2023 (Class C & D).

So the manufacturer of above devices as well as their raw material suppliers have to do compliance of all testing / qualification requirement laid down for the respective products.

Type of testing required for Raw Material & Components of Medical devices

1. Physical & Mechanical testing
2. Chemical testing
3. Microbiological testing
4. Biological Safety testing
5. Biocompatibility testing
6. Packaging testing
7. Stability testing
8. Electrical testing

1. Physical & Mechanical testing (As per BIS, EN, ISO & ASTM standards)

It includes Tensile and hardness testing, Scratch Resistance, Material fatigue testing, Static and fatigue product testing, Grain size evaluation, Microstructure analysis (phase analysis, etc.), Surface evaluations (alpha case, anodization) and Corrosion testing.

Tensile testing per ASTM E8 is routinely performed to evaluate cast, forged, and additively manufactured medical devices such as hip stems and knee femurs, and to verify mechanical properties of post-processed samples and materials. Tensile properties of titanium and cobalt chrome samples provide insight into how implants and materials will perform in service and are related to other mechanical properties such as fatigue and fracture toughness.

Equipment required for Physical and Mechanical testing are DSC (Differential Scanning Calorimetry), DMTA/DMA (Dynamic Mechanical Analyzers), TMA Thermomechanical Analyzers), TGA (Thermogravimetric Analyzer), HDT (Heat Desorption Temperature) and Universal Testing Machine.

2. Chemical testing (As per BIS, EN, ISO, ASTM & 21 CFR standards)

General chemical tests includes Molecular Weight (MW) of Polymers, Structure & Chemistry of fractions, End groups & Tacticity, Unreacted monomer and oligomers, Co-polymer content and blend composition, Catalyst residues, Contamination analysis, Chemical trace analysis and Plastics and Polymers volatile organic compounds testing.

Medical devices components chemical testing includes Identification of Extractable and Leachable chemicals, Forced Degradation Studies and Degradation Product Characterization, Stability studies including Accelerated and Stressed, Chemical and bio-analytical Characterization of Proteins, Peptides and Macromolecule Therapeutics, Specialist Surface Analysis and Surface Imaging, Integrated Study Management, Pre-clinical and Stage 1, Bio-analytical and Immunochemistry investigations, Pharmacopoeia Testing for Quality Control, Medical Device Polymer Materials Testing, DEHP and BPA Testing for Health Canada Medical Device Licensing, RoHS Testing Services.

3. Microbiological testing (As per BIS, EN, ISO, USP & ASTM standards)

Microbiological testing of a medical device refers to tests for the presence and risk of microbial contaminants. Methods may include mainly the testing of bio burden levels (Bio burden is a quantitative testing in which we only detect number of colony forming units (cfu)), Presence of endotoxin (Bacterial Endotoxin test, also

known as Limulus Amebocyte Lysate (LAL, which assesses medical devices coming in contact with cerebrospinal fluid or the cardiovascular system), and methods for sterility assurance.

Microbiological testing also includes Biofilm test, Anti-microbial test, Sterility testing (Sterility testing of medical devices are typically performed using media called SCDM (Soybean-Casein Digest Medium), which is physically placed in the media for fourteen days of Incubation time) & Microbial Barrier test.

Sterility assurance of medical devices is one of the requirements set forth by global medical device regulations. Ensuring consistent microbiological testing during manufacturing is imperative to product quality and patient safety.

All injectable and implantable devices need to be tested for endotoxin prior to being inserted into the patient. While the process of preparing a medical device for endotoxin testing and the endotoxin limit may vary from device to device.

4. Biological Safety testing for raw materials (As per IP/ BP/EP/JP/USP standards)

Raw materials of Medical devices includes PVC beads, HEPE beads, silicon, nylon, paper, Rubber beads, rubber closures, resin, coating material etc.

For raw material of medical device, biological safety study can be done by various compendial method given by IP/BP/ EP/JP/USP.

There tests includes - In-vitro cytotoxicity test

- Intracutaneous reactivity test
- Acute systemic toxicity test
- Implantation test

Over and above, some regulatory agency also asked for Material mediated Pyrogen Test (Using Rabbit) & abnormal toxicity test.

5. Biocompatibility testing of Raw Material / Components of Medical device (As per ISO 10993-1:2018 standards)

Risk & Toxicological assessment helps to understand the biological safety profile of the medical device product. Biological Safety testing is an assessment for biological effects from the exposure of a medical device or material to human body can include testing such as cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity, subchronic toxicity, genotoxicity, implantation and haemocompatibility, etc.

As per ISO 10993-1:2018, New MDR (for CE), USFDA and CDSCO, below mentioned testing required:

- Cytotoxicity testing (ISO 10993-5:2009)
- Sensitization testing (ISO 10993-10:2021)
- Intracutaneous test / Irritation testing (ISO 10993-23:2021)
- Acute systemic toxicity (ISO 10993-11:2017)
- Material mediated Pyrogen test (ISO 10993-11:2017)

Additionally in case of prolonged / long term exposure of component / device with the body, below mentioned additional testing are also required:

- Chemical Characterization Test (ISO 10993-18:2020)
- Extractable & Leachable Test (ISO 10993-18:2020 & ISO 10993-17:2002)
- Implantation test (ISO 10993-6:2016)
- Sub-acute / sub-chronic/ chronic toxicity test (ISO 10993-11:2017)
- Genotoxicity test (ISO 10993-3:2014)
- Hemocompatability testing (ISO 10993-4:2017)
- Degradation & Toxicokinetic (ISO 10993-16:2014)
- Carcinogenicity test (ISO 10993-11:2017)
- Reproductive toxicity test (ISO 10993-11:2017)
- Biological Risk Assessment (ISO 10993-1:2018)

Raw materials of Medical devices includes PVC tubes, Silicon Tubes, Nonwoven fabrics, HME filter, Packaging materials etc.

6. Packaging testing of Raw Material / Components of Medical device (As per BIS, ISO & ASTM standards)

All sterile medical devices require validation of their packaging. The sterile barrier must be shown to be effective throughout the product's claimed shelf-life.

According to ISO 11607-1, the specific properties of medical devices and their packaging systems must remain stable during their shelf life. Afterward, products can be subjected to various test systems in order to evaluate the performance of the packaging system, aseptic presentation and microbial barrier properties, as well as the performance of the containing medical device, functionality and biocompatibility. Validation of the packaging processes, such as the forming and sealing process of sterile barrier systems, pursuant to ISO 11607-2. In the course of a combined stability and packaging validation study, sterilized and final-packed test devices are subjected to both thermal and regular aging and to transport simulation, pursuant to ISTA or ASTM standards.

Packaging testing of raw material includes Dye test for Seal strength & integrity, Peel test, Burst test, Bubble test, Air permeability test and test for microbiological tightness,

Qualification of packaging materials, Validation of the forming, sealing and assembly processes of packaging for terminally sterilized medical devices, Validation of final packaging systems for sterile medical devices, Evaluation of the shelf life of the sterile packed medical device, Stressed medical devices are subjected to specific performance tests as well as to a biological evaluation test strategy.

7. Stability testing of Raw Material / Components of Medical device (As per ISO & ASTM standards)

The medical devices stability testing is the extent to which a device holds-on, within specified limits, and throughout its period of storage and use, the same properties, and characteristics that it possessed at its time of manufacture.

Similar to pharmaceutical products, medical devices have a set of criteria to evaluate stability such as Chemical (Degradation, Interaction, Device packaging and interaction, Radioactive decay, Manufacturing), Physical (Physical characteristics, Manufacturing process, Storage conditions), Microbiological (Sterility, Environmental control, Antimicrobial effectiveness), Therapeutic, Toxicological, Biocompatibility Testing.

Zones of stability testing are Accelerated stability study (ASTM F1980, ASTM D7160), Real Time stability study (ASTM F1980, ASTM D7160) and Transport stability testing / shipment system performance testing (ASTM D4169).

8. Electrical testing of Raw Material of Medical device (As per IEC & ASTM standards)

The International Organization for Standardization (ISO) and the International Electro-technical Commission (IEC) organizations based in Europe provide standards worldwide in partnership with the World Trade Organization. These include standards for electro-medical equipment. There are general and specific standards for medical device electrical safety. IEC 60601 is a series of technical standards for the safety and effectiveness of medical electrical equipment. The primary standard governing medical device design is formally known as IEC 60601-1 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

ASTM is one of the leading standards developers for medical devices. With 24 categories, addressing everything from surgical implements to automated analysis, ASTM medical device standards cover a truly wide range.

Electrical testing of raw materials includes Dielectric Constant/Dissipation Factor, Power Factor (ASTM D150, IEC 60250), Dielectric Strength (ASTM D149, IEC 243-1, IEC 60243), Volume Resistivity (ASTM D257, IEC 60093) and Surface Resistivity (ASTM D257, IEC 60093).

All above types of testing are schematically represented in Figure-1.

Conclusion:

After the enactment of Indian MDR, 2017 Act, CDSCO has frequently published various notifications to cover up 24 broad category of medical devices, which include approximate 2500+ devices, which are as of now not notified and have not regulated. CDSCO has given transition period till 30.09.2022 to all such class A & B devices (includes their raw materials) and till upto 30.09.2023 to all class C & D devices (includes their raw materials), after which any manufacturer of raw material as well as finished medical devices have to comply Indian MDR Rules, 2017 by doing all above mentioned testing.

About Author:

Dr. Manish A. Rachchh is working as a director (R & D) and CEO of Accuprec Research Labs Pvt. Ltd., Ahmedabad, Gujarat, India.

Accuprec is globally reputed medical device testing lab working with 200+ clients globally and accredited with FDCA, GLP, NABL, CPCSEA, ISO 9001:2015, AYUSH, DSIR, CDSCO & DUNS. Accuprec provides all above mentioned seven types of testing ranging from 1) Physical testing to 7) Stability testing (except electrical testing).

For any further information, you can write your query to manish.rachchh@accuprec.com & (M) +91-9099981023.

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   https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NzcwMQ

2. *Classification of non-notified medical devices – reg.*

   https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjQ1MA

How to Achieve Sustainability Goals: Solving 4 Challenges You May Face When Designing for Recycled Resins

Jessica Huang,

Marketing Specialist of CoreTech System (Moldex3D)

With climate change getting worse, people have become more conscious of their impact to the environment. Companies are receiving growing pressure to address ESG (Environmental, Social, Governance) concerns, striking a balance between their profitability and social impact. Environmental policies like Electronic Product Environmental Assessment Tool (EPEAT), 100% zero-emission vehicle (ZEV) acquisitions by 2035, and circular economy action plan are also stimulating companies to go greener. One important business goal is to achieve design for recycling and make products using recycled content. For instance, in automotive industry, Ford has been using ocean plastics to replace vehicle parts. Dell has developed easier-to-recycle computers and aims to integrate at least 50% of recyclates in all their products by 2030.

Although many have been implementing the concept of design for recycling and some already succeeded, it remains a challenging task. As a designer, you are very likely to face these problems during the product design process:

1. How to find suitable recycled materials that have similar properties as virgin plastics
2. How to reduce uncertainty when working with recycled materials
3. How to validate the right product designs and ensure product quality
4. How to reduce the cost of rework and scrap during manufacturing

These problems may seem daunting at first (and they are!), but they will be a lot easier when you have the right tools.

Moldex3D Material Center

Provide you with accurate recycled material information

Choosing ideal materials in the design phase is crucial to reduce the failure rate in production and guarantees good molding behavior. However, recycled plastics have very different physical properties compared to the virgin materials due to molecular structure breakdown and number of regrind cycles. To get accurate material data, you can submit a material testing request to Moldex3D Material Center, which is equipped with high-quality measurement instruments and ISO 17025 accreditation.

Fig. 1 Measurement instruments in Moldex3D Material Measurement Center

Our Moldex3D experts will run controlled measurement tests on the provided recycled material and virgin material. Material data will be available via a customized app, which will include shear viscosity from 5 different mixing percentages and how shear viscosity will be affected by the number of recycling, helping you find the blends with similar processing properties to the virgin plastic.

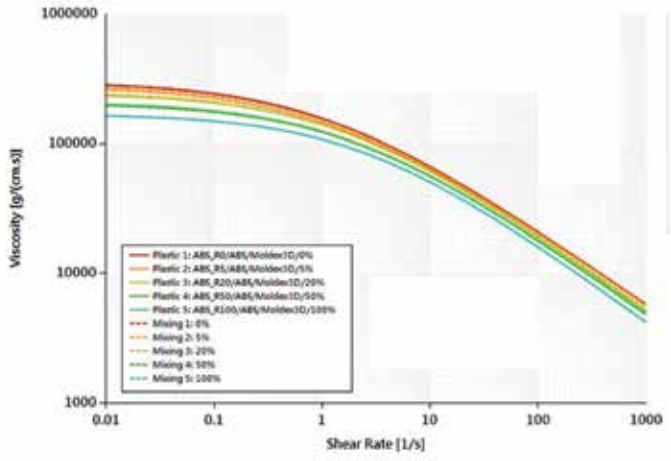


Fig. 2 recycled ABS-dependence of blending on viscosity

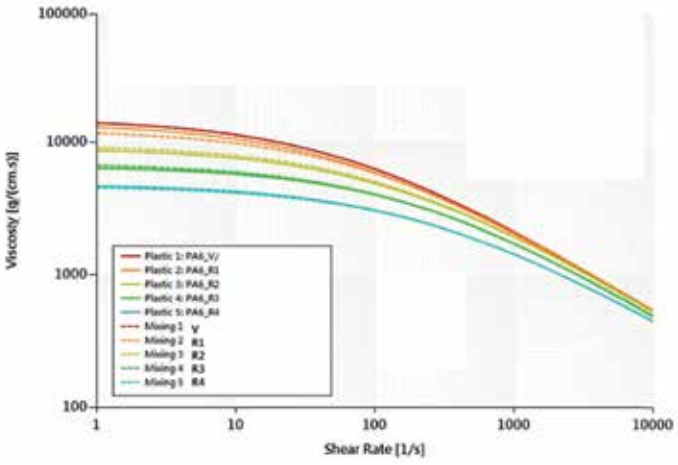


Fig. 3 Rheological properties for different number of recycling

This data can be applied into CAE analysis to ensure more accurate simulation, which will be further explained in the next session.

Moldex3D Molding Simulation Software

Simulate molding results to solve potential defects and validate design for recycling

When developing a new product design, we need to consider a lot of things:

1. How is the design for manufacturability (DFM)?
2. Does the product meet our quality standards?
3. Are there any potential design problems? (Shrinkage, warpage, sinks, internal stress, etc.)
4. Is this the most optimized design?

Design for recycling makes the process more complicated because the properties of recycled materials are different from virgin plastics and can largely affect the molding results. Also, many traditional design and manufacturing methods such as insert molding and adhesive bonding must be replaced by Design for Recycling techniques to create circular plastic products. Normally, we need to run a lot of mold tests and rely on molders' experiences to come up with the answers mentioned above. With Moldex3D molding simulation software and accurate material data, you can easily

- Validate your Design for Recycling (DfR)
- Identify potential design problems caused by material properties
- Find the most optimized solution

...All before mold trials!

For instance, the pictures below show a common problem when using recycled material. The viscosity of PP_R100 (recyclate) is higher than virgin plastic PP, because recycling has changed its material properties.

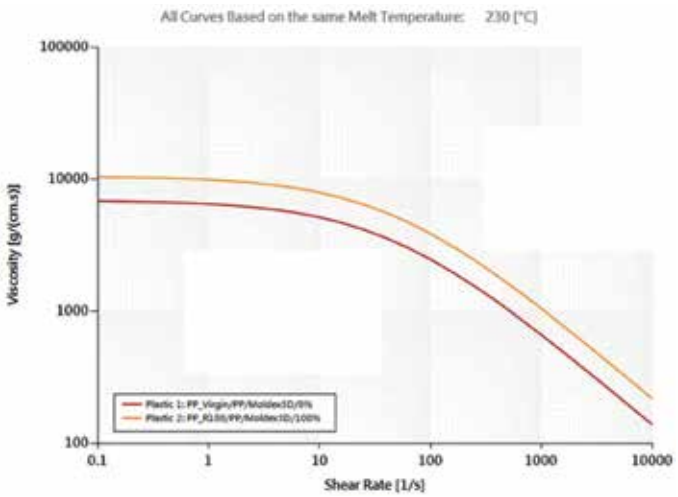


Fig. 4 Viscosity comparison between PP_virgin and PP_R100

Through Moldex3D simulation, the melt moves much slower than PP, leading to a severe flow hesitation. Short shots might occur at the end of the product.

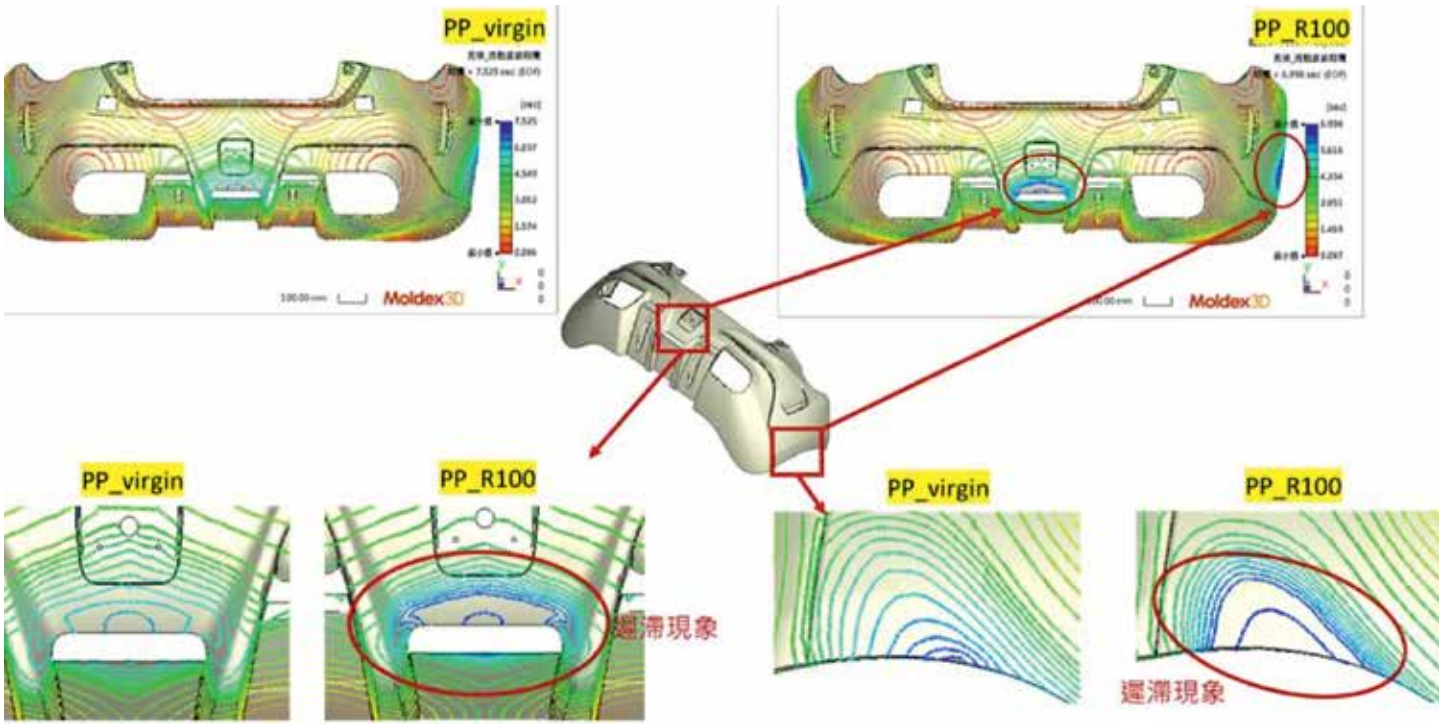


Fig. 5 Melt front comparison between PP_virgin and PP_R100

With this information in mind, we can adjust the processing conditions (melt temperature, mold temperature, flow rate, etc.) to fine-tune the viscosity curve and make it similar to the results of virgin material – PP to avoid potential design problems.

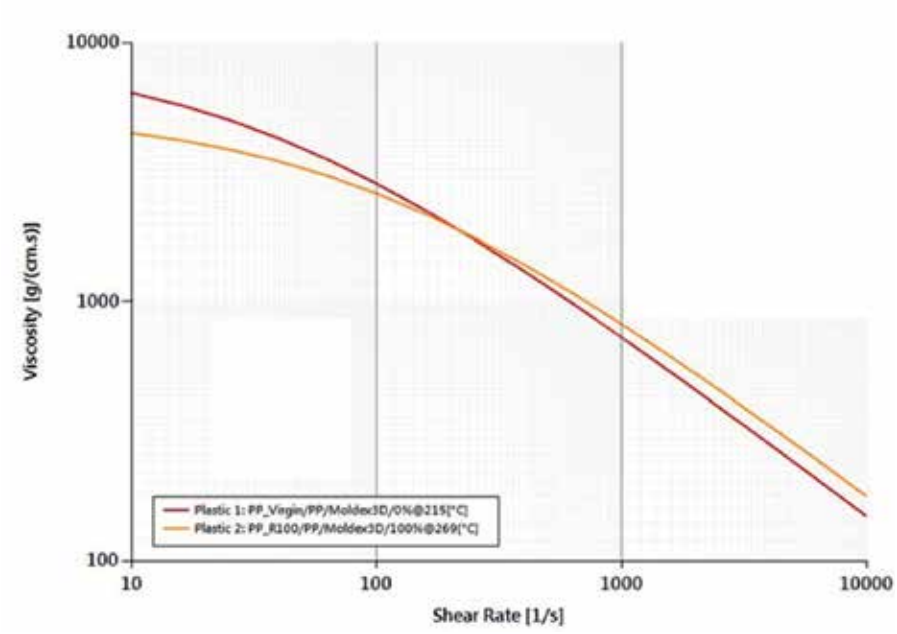


Fig. 6 Viscosity comparison between PP_virgin and PP_R100 (2)

When we run the simulation again using the new processing conditions and viscosity, we can see that the flow hesitation has been improved.

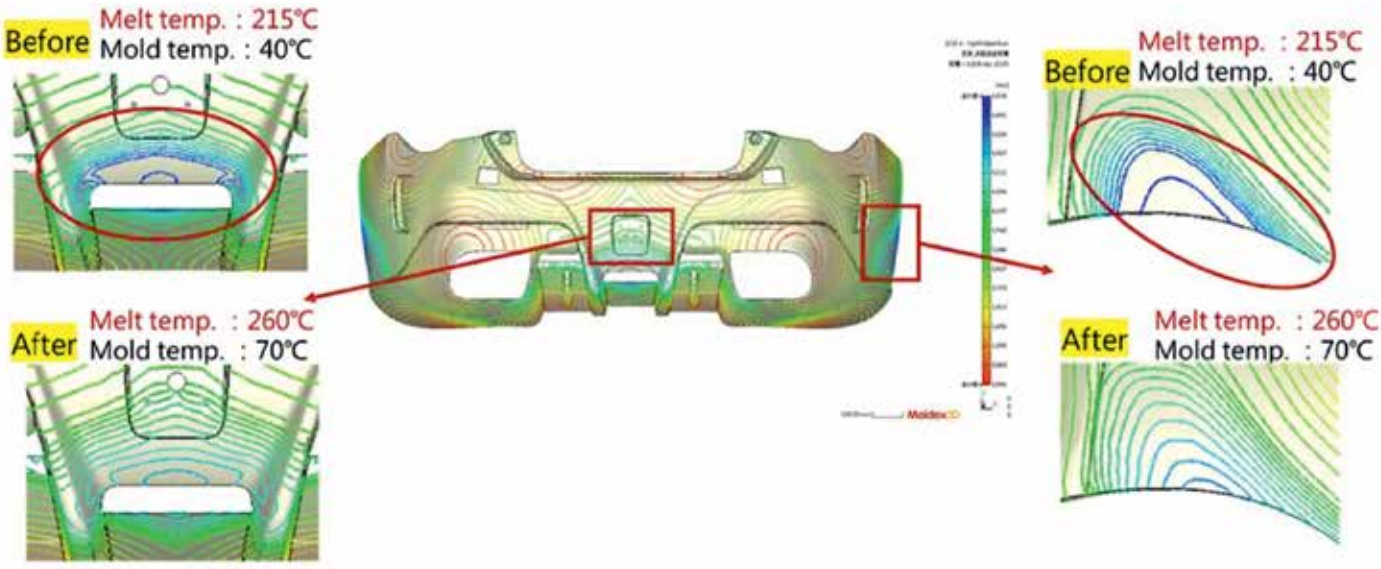


Fig. 7 Melt front comparison for PP_R100 before and after adjustment

Moldex3D simulation software can also help you predict part warpage, so you can make simulation-driven decisions to better alleviate potential molding defects.

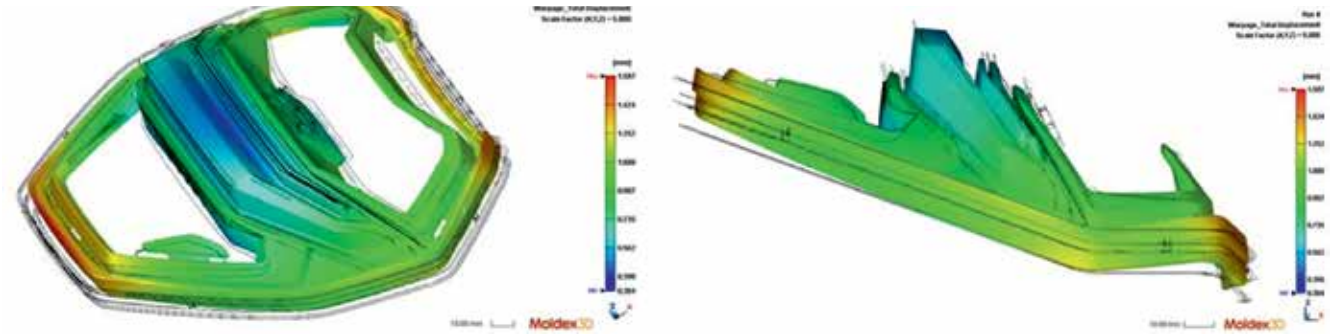


Fig. 8 Warpage - Total Displacement (Deformation)

After simulating and validating the product designs, it is important to store the data in a proper way. The entire molding workflow contains lots of valuable data and experiences, including material properties, machine specifications, Moldex3D CAE analysis projects, mold information, mold tryout conditions, and molding results, etc. With Moldex3D iSLM, a web-based platform for mold design and plastic engineering, the data can all be managed and utilized as an enterprise's database. No matter how many recyclates you are going to process, iSLM can help you store the critical data properly for future use.

In conclusion, with accurate material data and molding simulation software at hand, you get to test your design for recycling and find the most optimized solution within the fewest mold trials. What's more? You can simplify your production by reducing scraps and cost of rework during trials, achieving sustainability in a whole new level.

Feel free to reach out to us to schedule a demo. We will show you what can be done through simulation.

Or get 30-day trial from Moldex3D Material Hub and access 8,000+ material data.

PLASTIC TRYING TO BE HOLY THE HOLY GRILL 2.0

SAMEER JOSHI, Ph.D.

The Holy Grail is something that a person or group of people wish to achieve. As regards Holy Grail for Plastics, it is the intelligent way of sorting. Intelligent sorting of plastic packaging waste for recycling is poised to move forward. AIM the European Brands Association and the Alliance to End Plastic Waste announced a partnership in September 2021 to drive the next stage of development under the Digital Watermarks Initiative HolyGrail 2.0. They will work with the city of Copenhagen to conduct the semi-industrial test phase of the pilot. This milestone will be one step closer to precision identification and sorting of plastic packaging waste through digital watermarks, with the potential to revolutionize the sorting and recycling process of packaging.

Digital watermarks are discrete codes, each the size of a postage stamp. They cover the entire surface of a consumer goods packaging and carry a wide range of attributes such as packaging type, material, and usage. Used packaging is collected and scanned on the sorting line with a high-resolution camera which detects and decodes the digital watermark. The packaging is then sorted into corresponding streams, based on specified attributes including food, nonfood, or polymer types. This leads to more accurate sorting streams and higher quality recyclates to be diverted back into the plastic packaging value chain.

Over four months, a prototype sorting detection unit will be installed at the Amager Resource Centre (ARC) in Copenhagen, where the trials and demonstrations with around 125,000 pieces of packaging representing up to 260 different stock-keeping units (SKUs) will be held. Engineers will test for several parameters including the speed and accuracy of the system, to ensure its ability to withstand the pressures of full-scale industrial operations.

Sorting machinery Manufacturers Pellenc ST and Tomra come (delete) together with the selected digital watermarks technology provider Digimarc are developing add-on modules for their detection sorting units, to be combined with existing near infra-red (NIR) sorters. Both modules will be tested during the semi-industrial phase via trials at two different test locations. The first controlled tests using industrial-sized equipment and the Pellenc ST/Digimarc module are scheduled for October 2021 at ARC sorting centre.

During this commercial test phase, consumers will buy on-shelf products with digitally watermarked packaging. Used packaging will enter the waste stream after consumption. The sorting units will be placed in five different locations in France and Germany, including MRFs (Materials Recovery Facility), PRFs (Plastic Recovery Facility) and recycling plants.

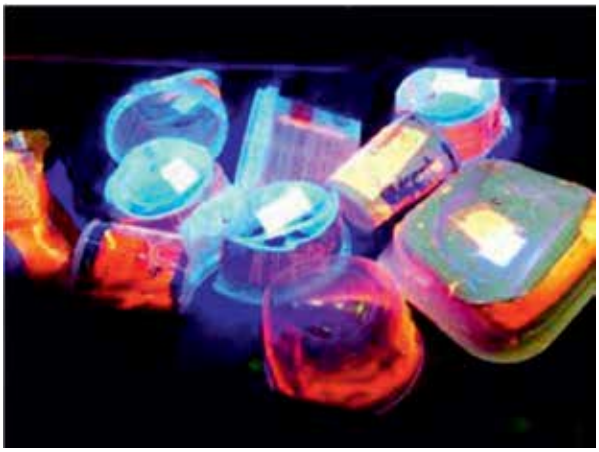
Copenhagen has a political ambition to become the world's first carbon neutral capital by 2025, says Merete Kristoffersen, Head of Division, Waste and Resources, City of Copenhagen. High quality plastic recycling that substitutes new production and reduces incineration is a key instrument to reach this goal. HolyGrail 2.0 has the potential to achieve this, and we look forward to doing our part in the testing of the technology."

Stakeholder perspectives.

This milestone marks the second year of the HolyGrail 2.0 project. Since its launch in September 2020, it has grown to include more than 130 participating companies and organizations across the complete packaging value chain. The pioneering HolyGrail 1.0 was facilitated by the Ellen MacArthur Foundation in 2016

And why the curious name? Is the technology so promising that it could be, in fact, the answer in regards to efficiently sorting recycling Digital watermarking has the potential to become the holy grail of packaging recycling."

Henkel is one of the project pioneers, and has already released a product, its bottle for Vernel fabric softener, which contains this technology. It has been released in Germany,



One of the main goals of the EU Plastics Pact (and, indeed, the US and UK Plastics Pacts as well) is to create a circular economy for plastics. This means that materials are kept in use for as long as possible, and nothing is wasted. Developing technologies and improving efficiencies around recycling is an important lever in moving towards this goal. Indeed, the precursor to HolyGrail 2.0 was an initial exploration under the New Plastics Economy initiative run by the Ellen MacArthur Foundation to look into chemical tracers and digital watermarking.

Chemical tracing involves embedding a marker in the label or plastic resin that shows up fluorescent under UV light, so it can be detected by specially designed sorting machines. Although an interesting technology, it was decided that digital watermarking was the more promising of the two technologies and, thus, it became the sole focus of HolyGrail 2.0.

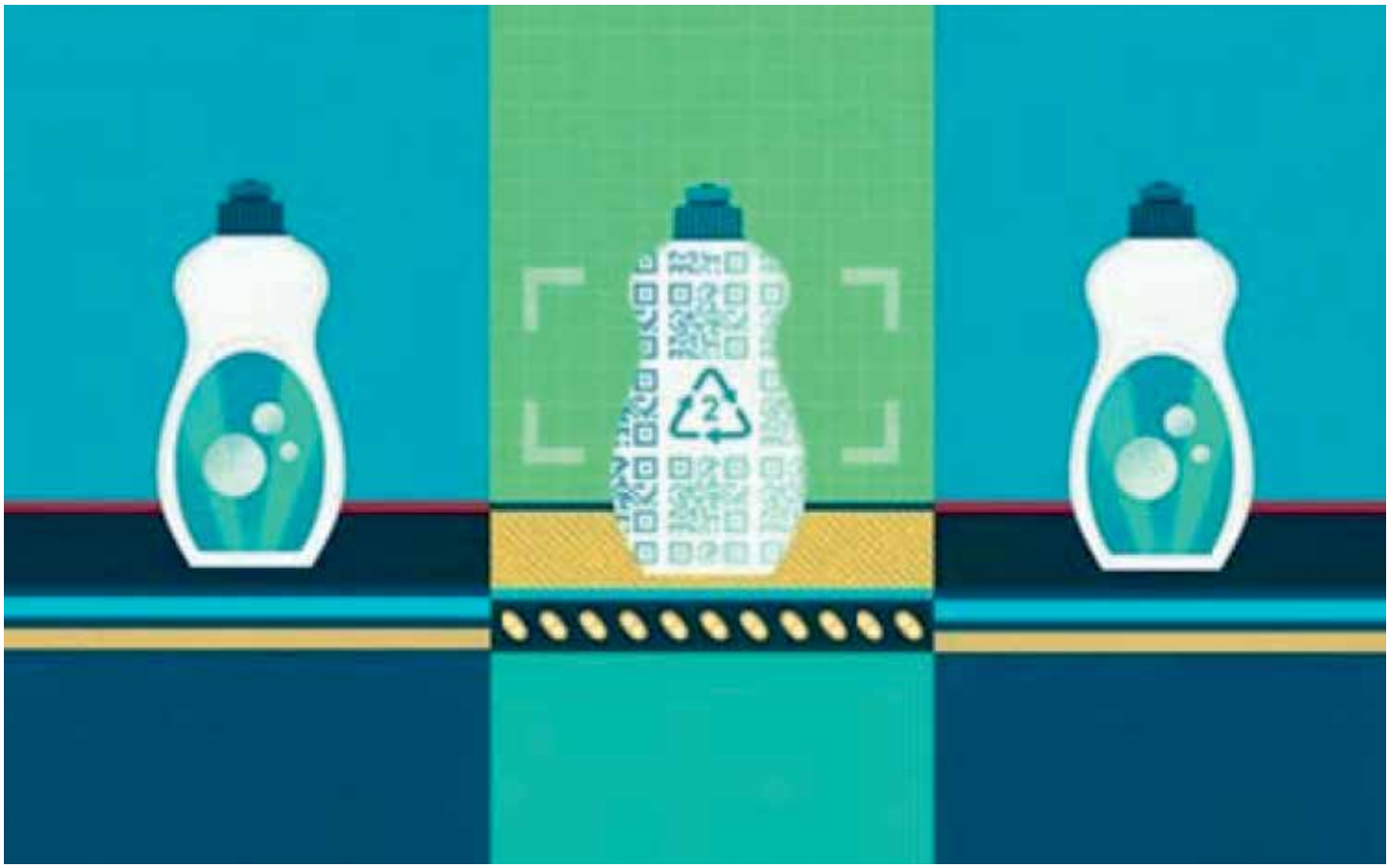
It brings big advantages, especially in the retail space. At the checkout in a store, the entire item could be scanned, instead of the barcode that sometimes takes a while to find. This means that checkout times could be decreased by 30% or so, which is a very interesting benefit for retailers.

The team behind Holy Grail 2.0 is actively looking into all these applications, but Schneider is keen to point out that the main focus is to pioneer solutions around smart packaging. "One of the most pressing challenges in achieving a circular economy for packaging is finding a way to accurately sort post-consumer waste. Digital watermarks have the potential to revolutionize this process," she says. "The Holy Grail 2.0 initiative combines the three key ingredients needed for a circular economy: innovation, sustainability and digitalization. Initial proof-of-concept demonstrations have already shown what digital watermarks can achieve on a test sorting line. Now, it's time to take this testing to the next level."

"An initiative like this can only thrive with the wide support of different key stakeholders in terms of expertise, but of course also financial support. Collaboration is the way forward to achieve the EU's circular economy goals and we are confident that this technology has the potential to drive a truly circular economy for packaging."

"Recycling is a key pillar that must be invested in to advance a circular economy in plastic waste. The Alliance is excited to support the scaling of this project in its next phase of progress, in line with our mission to end plastic waste in the environment," says Jacob Duer, President and CEO of the Alliance. "As testing continues, we know there will be many things to solve along the way, but with strong collaboration of our public and private sector partners, we believe intelligent sorting can be a new frontier that could help dramatically improve plastic waste management."

(INPUTS – PLASTIC TODAY, HENKEL)



Seminar on "Latest Technological Innovation in PE / PVC / CPVC Pipes & Fittings Technology






Indian Plastics Institute HO and Ahmedabad Chapter jointly with Saurashtra Plastics manufacturers Association (SPMA) & Indian Vinyl Council (IVC) organized a Half Day Seminar on 22/06/2022 on "Latest Technological Innovation in PE / PVC / CPVC Pipes & Fittings Technology" was held from 3.30 p.m. onwards at Hotel The Imperial Palace, Dr. Yagnik Road, Jaganath Road, Rajkot, Gujarat.

The Seminar received a great response with more than 300 Online Registered Participants. The Registration was closed one day before the seminar date as the registration went above the capacity of the seminar venue. We had witnessed such a response for the first time. The Physical participant count on the day of the Seminar was +275

The Presenters were:

- Mr. Jagat Choksi Director Basil Prompt Vinyl Ltd
- Mr. Chanchal Dasgupta Manager (Appln. Mktg. Infrastructure) Borouge India Pte. Ltd.
- Mr. Yash Parikh Director Neoplast Engineering Pvt. Ltd.
- Mr. Vishal Saxena and Mr. Sanjay Tiwary ExxonMobil Company India Pvt. Ltd.
- Mr. Himanshu Jani and Mr. Abhimanyu Hada Milacron India Pvt. Ltd.
- Mr. Sandeep Bhuva CEO Rajoo Bausano Extrusion Pvt. Ltd.
- Mr. Ritesh Shah Windsor Machines Ltd
- Mr. Manish Jain Representing Indian Vinyl Council

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- Shibaura Machine India Private Limited (abbreviated as SMI), is among the leading high-end plastics injection molding machines and auxiliary equipment manufacturers in India. SMI is a wholly owned company of Shibaura Machine Company of Japan.
- With decades of experience in plastics machinery segment, we help hundreds of companies around the world to mold products with precision & speed, offering very high-quality of output. With Shibaura Machine factories spread across Japan, China, Thailand, and India, we offer competitive products and services to our clients that would equip them with a leading edge in market place. Our comprehensive service network and application knowledge across segments help clients to choose the right product for their requirement and would optimize the production with a very high up-time.
- The entry and mid-level hydraulic machines in clamping force ranging from 400kN to 13000kN are manufactured at our state-of-the-art factory in India and caters to application segments in packaging, electrical, automotive, white goods, writing instruments, construction etc.

CORETECH SYSTEM CO., LTD. (Moldex3D)

CoreTech System Co., Ltd. (Moldex3D) was founded in 1995, it has provided the professional plastic injection molding simulation solution "Moldex" series for the plastic molding industry, and the current product "Moldex3D" is marketed worldwide.

Committed to providing the advanced technologies and solution for industrial demands, CoreTech has extended the worldwide sales and service network to provide local, immediate, and professional service. Nowadays, CoreTech presents the innovation technology, which helps customers to troubleshoot from product design to development, to optimize design pattern, to shorten time-to-market, and maximize product ROI.

OUR PATRONS

SENTHIL PLASTIC CONTAINERS

Senthil Plastic Containers was established in the year 2006 and engaged in the manufacture of plastic paint pails of various sizes and other injection moulded components as per customer specifications and moulds.

The company has a modern and state of art manufacturing facility to develop the products on understanding the customer need for quality performance and application, translate the need into product chemistry, and develop the cost-effective value-added product. The company's products are widely used by large, medium, and small industries throughout the country.

The main aim of Senthil Plastic Containers is to satisfy the customers by providing supplier service and quality products. The organization implemented ISO 9001: 2008 Quality Management System integrated with other applicable standards and systems with the aim of assuring effective production and quality of products as well as enhancing customer satisfaction.

What we do

We are one of the emerging manufacturers and suppliers of high-quality injection moulded components. We supply our products across various industries like Paint, Lubricant, Ink and Dyes, Food Packing (Curd, Ghee, Biryani, Pickles, Gherkins, Honey), and Agro Chemicals, Pharma Products, Animal feeds, Domestic household Products, etc. We strictly follow the QCDS concept in our business which helps us to grow continuously.

INFINITE CERCLE PVT LTD

Infinite Cercle Pvt Ltd is one of the Scrap Trading company based in Coimbatore, India. We are involved in trading with Plastic Scrap, Metal Scrap, Paper Scrap, and Rubber Scrap. The main motive of our company is to avoid the waste material reaching to landfill. We establish a strong scrap business deal with reliable scrap traders from all over the world.

What Cerclex do

- "Helping Brands to make our planet Better"
- "The Reliable smart waste management system you have been searching for"
- Cerclex delivers real-time actionable insights of waste management to track & trace from acquisition to extinction.
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Our Institute publishes a bi-monthly "IPI Journal" disseminating information both on technical and general subjects of interest to our Members. Our circulation is around 2900 copies, but readership can be around 25000.This is a technical Journal and all our members are technical professionals from Plastics Industries, they share the Journal amongst' their colleagues. This Journal is mailed free of cost to all our – 2900- members.

The Journal disseminates technological developments taking place in the Plastics Industry all over the globe. We have to be published an IPI Journal December – January 2023 Special Issue in Plastindia 2023 Exhibition.

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To ensure all IPI Members receive immediate information on email and/or other quick communication modes and also update ipi records, may we request all IPI Members kindly forward the enclosed Membership Data / Update Form of IPI Members duly filled in with all the particulars, either on email info@ipiindia.org or by post/ courier as IPI Office address, Mumbai.

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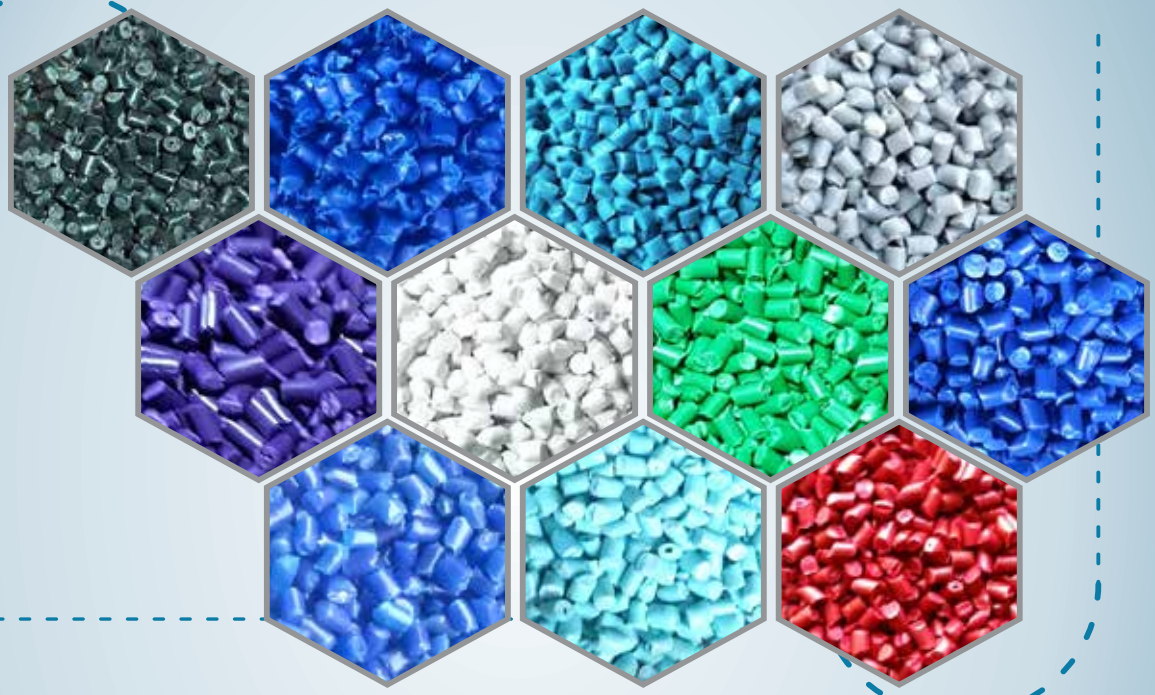

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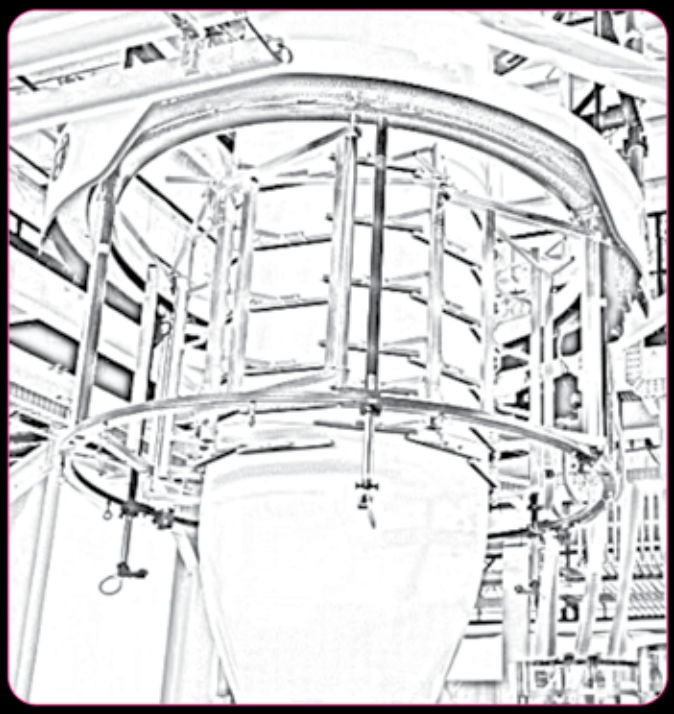

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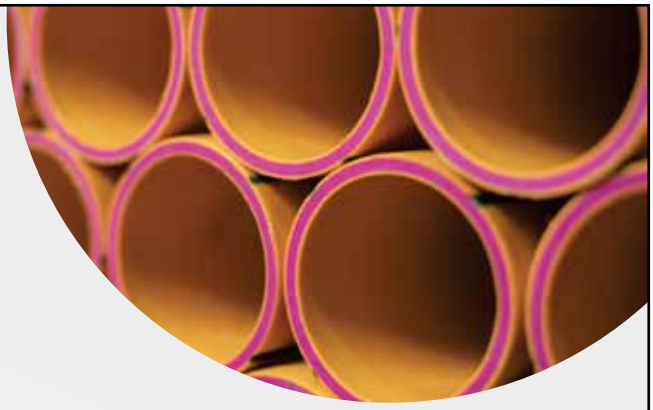

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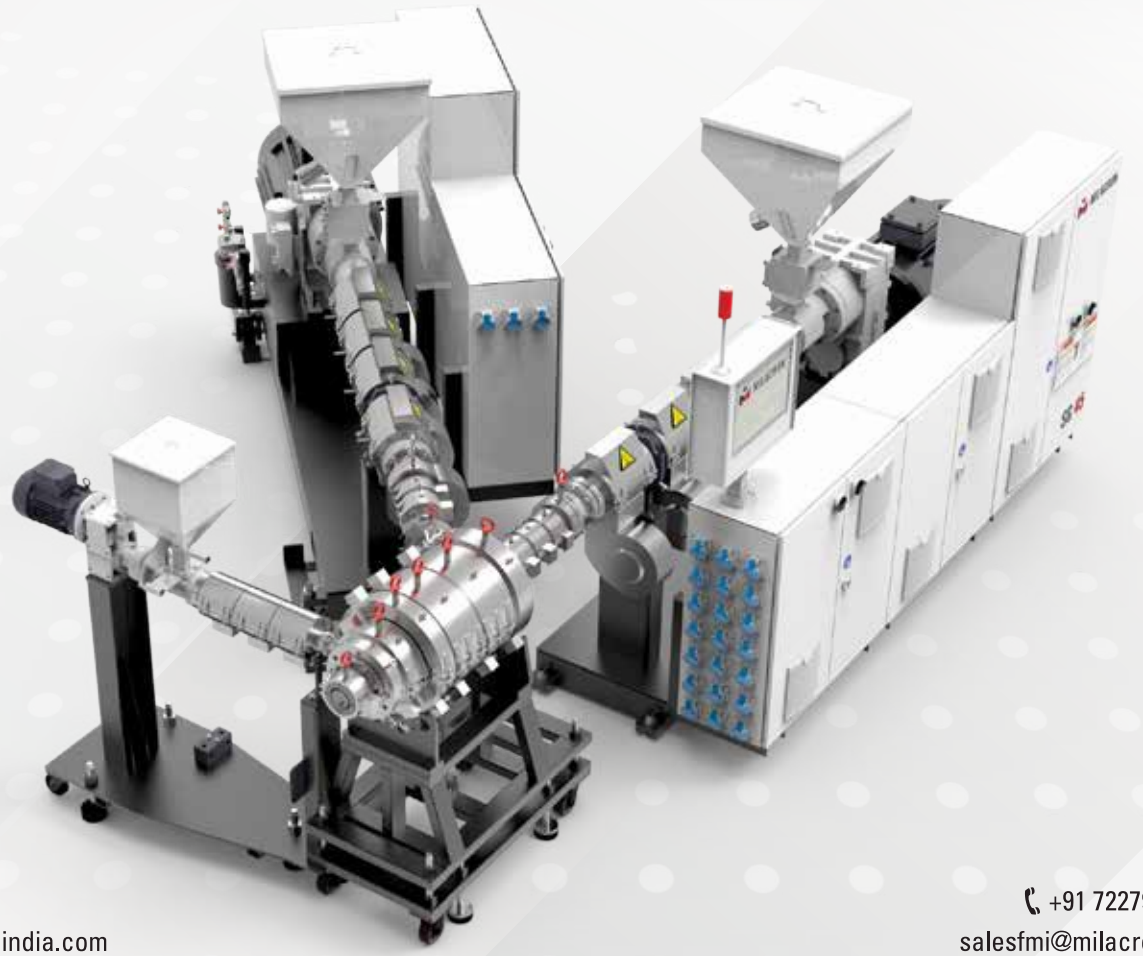

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